

EXHIBIT A-1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA et al.,) CASE NO. 12-7758 (ZHQ)(JBD)

ex rel. JESSICA PENELOW AND) OPINION

CHRISTINE BRANCACCIO,)

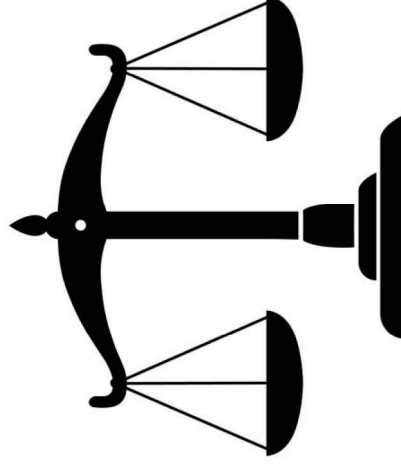
Plaintiffs,)

v.)

JANSSEN PRODUCTS, LP)

Defendants.)

_____)



Prof. Shaked's Presentation
June 3, 2024

Statistical and Economical Analysis

Prof. Shaked's Credentials

Prof. Shaked's Credentials



- ❑ Doctor of Business Administration (DBA), Harvard Business School.
- ❑ Master in Business Administration (MBA) in Finance, BA in Economics, BA in Statistics
- ❑ Over 43 years: Professor of Finance and Economics, Boston University.
- ❑ Over 35 years: Co-Founder and Managing Director of The Michel-Shaked Group.
- ❑ Authored several books and numerous academic and trade articles.

Prof. Shaked's Credentials



- ❑ Testified before the U.S. Congress's House Ways and Means Committee.
- ❑ Testified on behalf of and opposed to the Internal Revenue Service (IRS).
- ❑ Consulted the U.S. Department of Justice (DOJ).
- ❑ Consulted/Analyzed the Federal Deposit Insurance Corporation (FDIC).
- ❑ Consulted/Analyzed numerous companies in a wide range of industries, including:
 - Pharmaceuticals: Plantex, Pfizer, Chiron, Novartis, Teva Pharmaceutical, Merck, Schering-Plough, and Bayer AG
 - Pharmacies: Allion HC, Cardinal Health, FoxMeyer Corp, McKesson HBOC, Walgreen, Guardian Pharmacy of Atlanta, TridentCare (radiology), and PharMerica

Scope of Engagement

Scope of Engagement

- In relation to Janssen Products, L.P.'s ("Janssen's") business from June 2006 to December 2014, I was requested to analyze and opine on:
- The total compensation paid to physicians¹ serving on Janssen's Prezista and Intelence Speaker Bureaus;
 - The relationship between compensation paid to speakers and their subsequent levels of P&I prescriptions ("Rx");
 - The relationship between Janssen's off-label marketing and physicians' subsequent levels of off-label P&I Rx;
 - Total amount of damages relating to Janssen's alleged:
 - Unlawful kickbacks paid to doctors; and
 - Off-label marketing of its HIV drugs Prezista and Intelence ("P&I"), in violation of the False Claims Act;

(1) Physicians are defined as all health care professionals who prescribe medication to patients.

Case Background

Janssen's HIV Drugs: Prezista & Intelence

Medical Terminology

- ❑ Janssen started selling the antiretroviral ("ARV") drugs Prezista and Intelence, in June 2006, and January 2008, respectively.¹

❑ Medical terminology:

- Antiretroviral drugs: drugs used to treat HIV/AIDS.
- Treatment-experienced: refers to patients who have previously taken ARV drugs.
- Treatment-naïve: refers to patients who have NOT previously taken ARV drugs.
- Combination treatment: a treatment that includes more than one unique ARV drug.
- Once-daily vs. twice-daily: daily drug dosage frequency.
- Protease Inhibitors ("PI") : Class of ARV drugs that Prezista is a part of.
- NNRTI:² Class of ARV drugs that Intelence is a part of.

(1) BTIG research report, *Initiating Coverage*, "Johnson & Johnson: Improving Growth Outlook into 2017...", October 29, 2015, p. 30; *Drugs.com*, "FDA Approves Intelence," (<https://www.drugs.com/newdrugs/fda-approves-intelence-etravirine-hivcombination-therapy-813.html>).

(2) Non-nucleoside reverse-transcriptase inhibitor.

Janssen's HIV Drugs: Prezista & Intelence

Prezista

US FDA Approval Timeline for Prezista Use:

June 2006	October 2008
Accelerated approval for combination treatment of <u>treatment-experienced</u> HIV Adult Patients	Once-daily for combination treatment of <u>treatment-naïve</u> HIV Adult Patients & Twice-daily for <u>treatment-experienced</u> patients

Prezista's adverse reactions include increased lipid levels.

Source: BTIG research report, Initiating Coverage, "Johnson & Johnson: Improving Growth Outlook into 2017...", October 29, 2015, p. 30.

Janssen's HIV Drugs: Prezista & Intelence

Prezista Rx Reimbursed by Government Payors: Medicare, Medicaid and ADAP



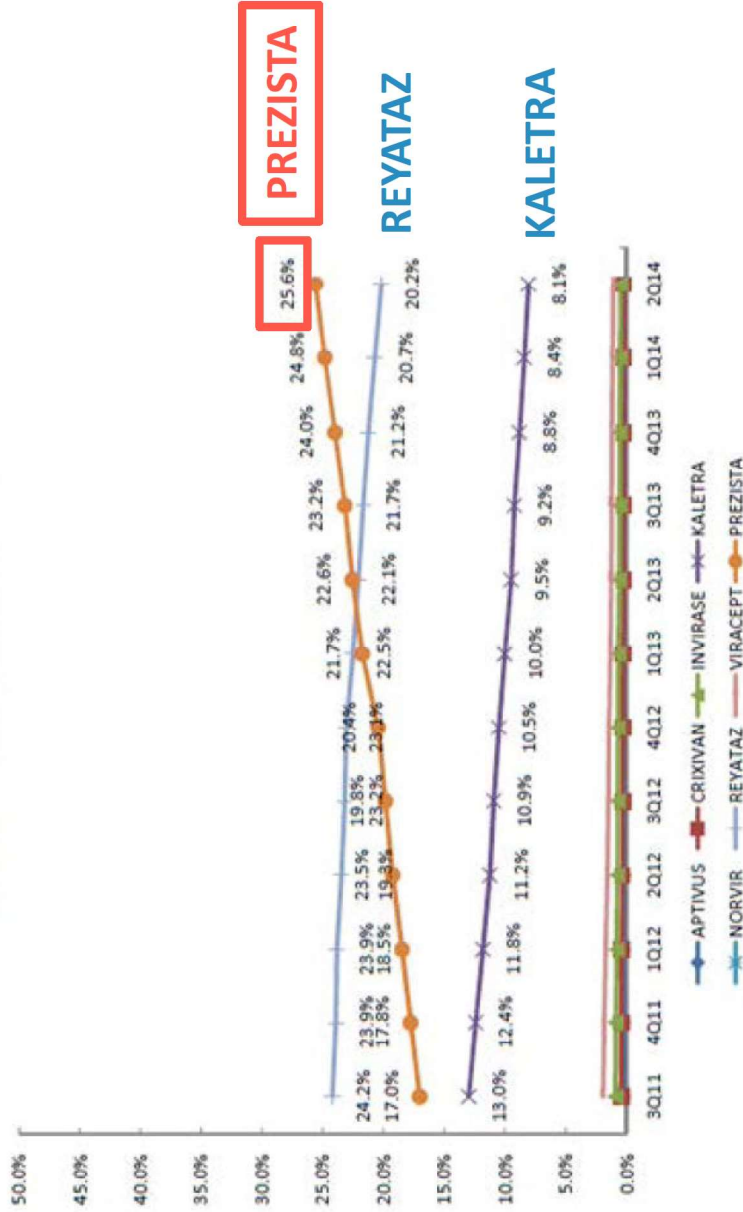
Source: CCW and ADAP database.

Janssen's HIV Drugs: Prezista & Intelence

Prezista

- Compared to other protease inhibitors, the market share of Prezista was the fastest rising from mid-2011 to mid-2014, reaching a market share of 25.6% by the second quarter of 2014.¹

Total TRx Market Share



(1) BMO Capital Markets research report, *Initiating Coverage*, "Johnson & Johnson: Initiating Coverage with an Outperform Rating," September 4, 2014, p. 49.
(2) TRx stands for total prescriptions.

Janssen's HIV Drugs: Prezista & Intelence

Intelence

Intelence was never approved for treatment-naïve patients or for once a day dosing.

Sources: Drugs.com, "FDA Approves Intelence," (<https://www.drugs.com/newdrugs/fda-approves-intelence-etravirine-hivcombination-therapy-813.html>); Drugs.com, "U.S. Food And Drug Administration (FDA) Grants Traditional Approval for Intelence (etravirine)," (<https://www.drugs.com/newdrugs/u-s-food-administration-fda-grants-traditional-approval-intelence-etravirine-1790.html>); Drugs.com, "FDA Approves Intelence for Pediatric Patients," (<https://www.drugs.com/newdrugs/fda-approves-intelence-etravirine-experienced-pediatric-patients-hiv-1-following-priority-review-3155.html>).

Janssen's HIV Drugs: Prezista & Intelence

Intelence Rx Reimbursed by Government Payors: Medicare, Medicaid and ADAP



Source: CCW and ADAP database.

Kickbacks and Off-Label Marketing

Kickbacks and Off-label Marketing



Allegedly, Janssen marketed off-label information about P&I to physicians. The following physicians are considered to be “influenced:”

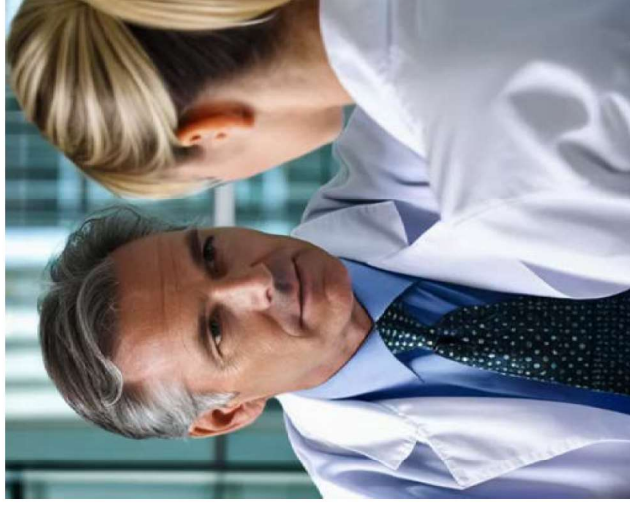
1) Speaking at a speaking event



2) Attending a speaking event



3) Receiving Janssen’s marketing from a sales representative



Off-label Marketing of Prezista

Janssen's Prezista Off-label Claims: Definitions

Lipids Claim

- All Prezista Rx, written for patients who received any lipid regulating medication or a lipid-related diagnosis prior to the first time they were prescribed Prezista.

Treatment Naïve Claim

- All Prezista Rx (June 2006 - September 2008), written for patients who previously were not taking any ARV medication.¹

(1) Patients who did not have an Rx for another ARV medication prior to that patient's first Prezista Rx, and who have not received an Rx for a non-Prezista ARV drug within 90 days following their first claim of any kind.

Off-label Marketing of Intelence

Janssen's Intelence Off-label Claims: Definitions

☐ Treatment Naïve Claim

- All Intelence Rx, written for patients who previously were not taking any ARV medication.¹

☐ Once-Daily Dosing Claim

- All Intelence Rx with once-daily dosage.

(1) Patients who did not have an Rx for another ARV medication prior to that patient's first Intelence Rx, and who have not received an Rx for a non- Intelence ARV drug within 90 days following their first claim of any kind.

Kickbacks and Off-label Marketing: Damages

Kickbacks

Janssen providing
kickbacks to speakers



Damages: All speakers' P&I
Rx after their first speech

Off-label Marketing

Janssen providing off-label
marketing to physicians



Damages: All influenced
physicians' initiated +
attributed off-label P&I Rx (\$)

Anti-Kickback Analyses: Speaker Compensation and Rx

Anti-Kickback Analyses: Speaker Compensation

Speaker Compensation

- ❑ I calculated the total annual amount of compensation paid by Janssen to all speakers (2006 to 2014) for the following five categories:

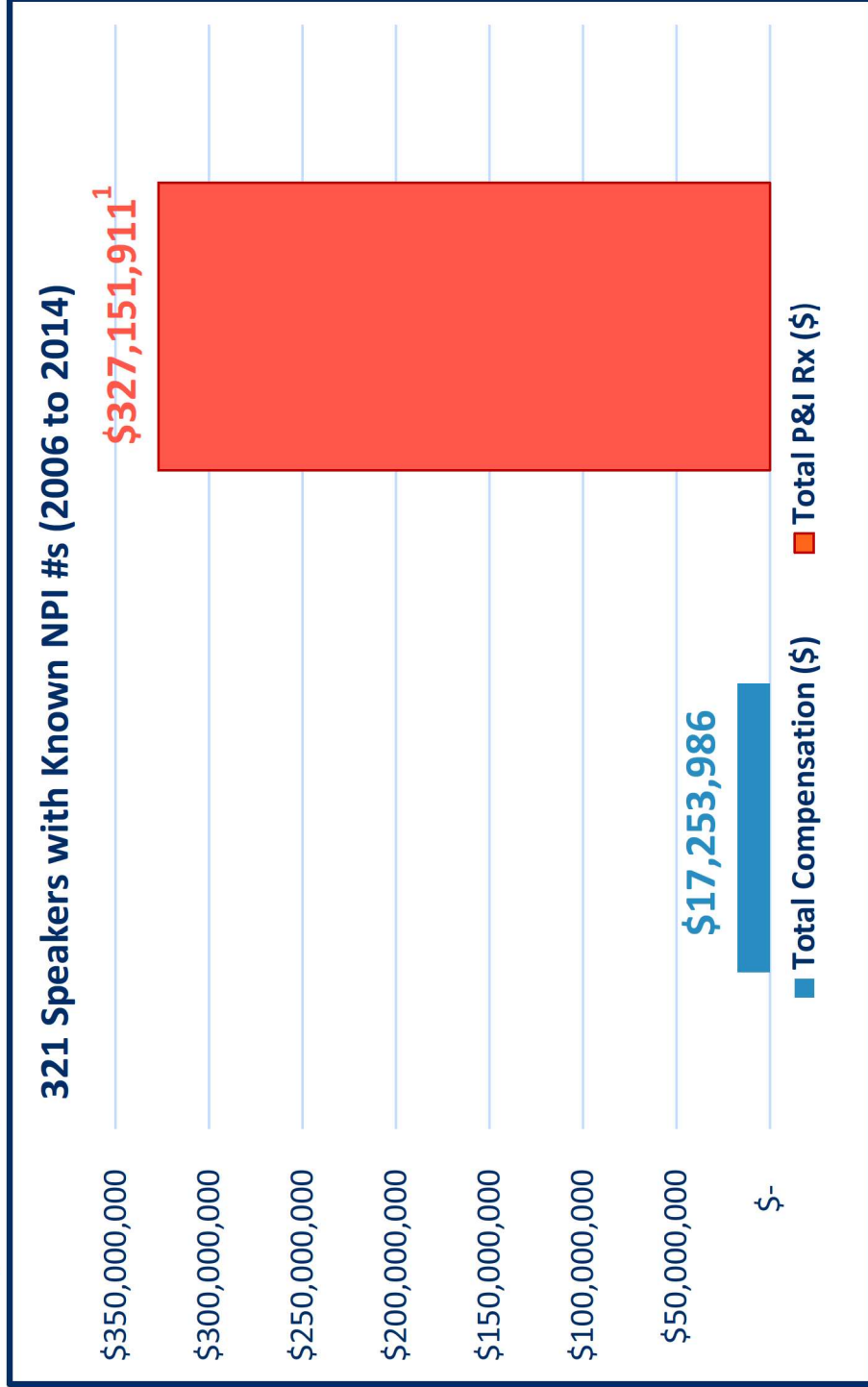
Year	Honoraria	Speaker Training Fees	Speaker Expenses	Consulting Fees	Consulting Expenses	Total Compensation
2006	\$ 573,750	\$ -	\$ 34,276	\$ -	\$ -	\$ 608,026
2007	\$ 708,050	\$ 14,000	\$ 23,432	\$ -	\$ -	\$ 745,482
2008	\$ 1,749,250	\$ 214,800	\$ 103,060	\$ 3,000	\$ 44,933	\$ 2,115,042
2009	\$ 2,077,500	\$ 33,050	\$ 75,375	\$ 157,500	\$ 68,407	\$ 2,411,832
2010	\$ 2,203,750	\$ 101,250	\$ 344,137	\$ 135,350	\$ 59,825	\$ 2,844,312
2011	\$ 2,579,350	\$ 157,000	\$ 463,924	\$ 105,762	\$ 30,688	\$ 3,336,724
2012	\$ 1,840,350	\$ 100,000	\$ 237,838	\$ 103,000	\$ 29,504	\$ 2,310,692
2013	\$ 867,300	\$ 30,700	\$ 76,219	\$ 101,624	\$ 26,701	\$ 1,102,544
2014	\$ 1,500,350	\$ 17,250	\$ 213,707	\$ 38,620	\$ 9,404	\$ 1,779,331
Total	\$14,099,650	\$ 668,050	\$1,571,968	\$ 644,857	\$ 269,461	\$ 17,253,986

Note: Analysis based on 321 speakers who had a known National Provider Identifier ("NPI") number (Medicare and Medicaid). Total compensation calculation excludes all attendee-related expenses.
Source: Expert Report of Prof. Shaked, Exhibit 11-2.

Anti-Kickback Analyses: Speaker Compensation

Speaker Compensation vs. Speaker P&I Rx (\$)

- Total compensation and P&I Rx (\$) for all 321 paid Janssen speakers who had a known NPI number (for the period 2006 to 2014):



Note: (1) Does not reflect the patients' typical life-long prescriptions following 2014.

Source: Expert Report of Prof. Shaked, Exhibit 14.

Anti-Kickback Analyses: Speaker Rx Levels

Speakers Continued to Prescribe P&I Once They Started Giving Paid Speeches

The dollar amount of P&I Rx¹ from speakers' first speech through 2014:²

Over \$327.2 million of speakers' P&I Rx income reimbursed by government.³

Notes:

(1) The dollar amount of P&I Rx is defined as "P&I Rx \$"

(2) Does not reflect the patients' typical life-long prescriptions following 2014.

(3) Analysis based on 321 speakers who had a known National Provider Identifier ("NPI") number, and who received compensation from Janssen (Medicare, Medicaid and ADAP).

Source: Expert Report of Prof. Shaked, Analysis 1.

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

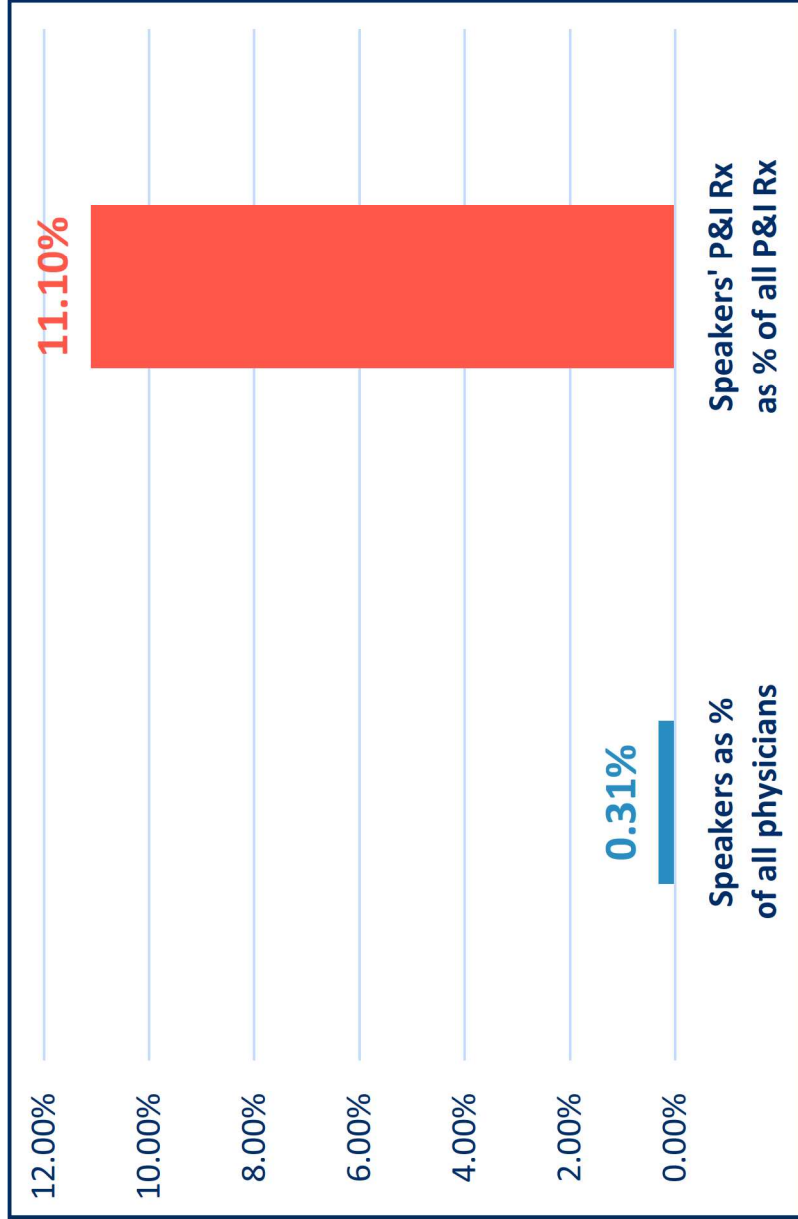
Speakers Prescribed 11% of All P&I Rx, While Accounting for Only 0.31% of All Physicians Who Prescribed at Least 1 ARV Drug 2006-2014

		Total Government	
	# of Physicians	Reimbursed P&I Rx	
Speakers	335	\$	327,151,911
All Physicians	109,306	\$	2,946,410,440
Speakers as % All	0.31%		11.10%

Note: Analysis based on Medicare, Medicaid and ADAP data.
Source: Expert Report of Prof. Shaked, Analysis 3.

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

Speakers Prescribed 11% of All P&I Rx, While Accounting for Only 0.31% of All Physicians Who Prescribed at Least 1 ARV Drug 2006-2014

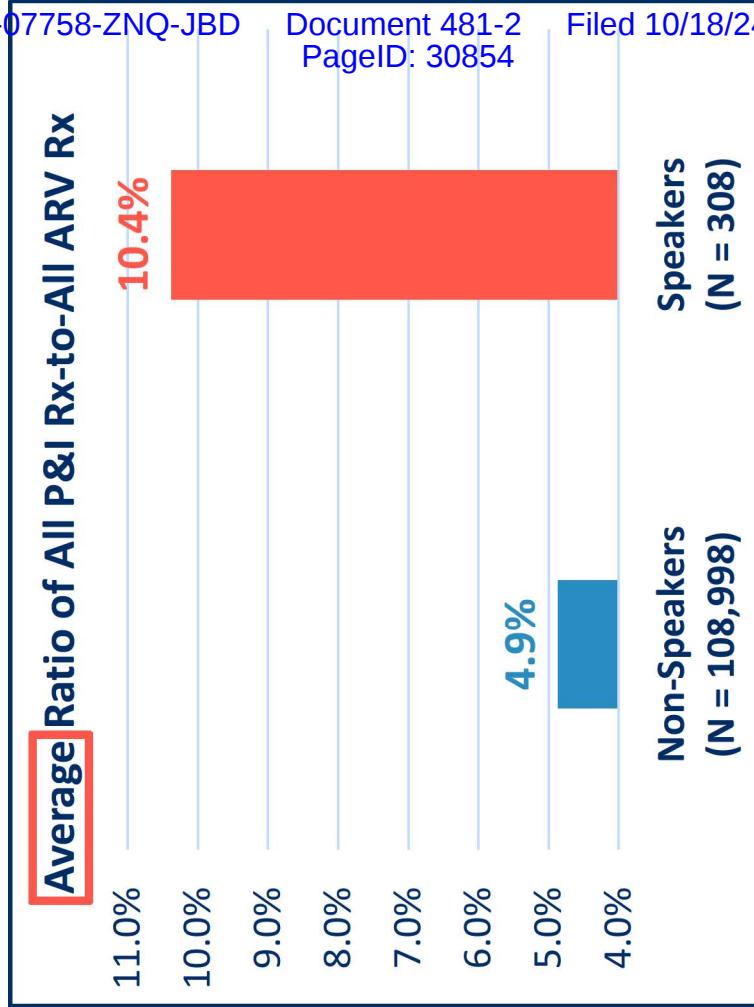
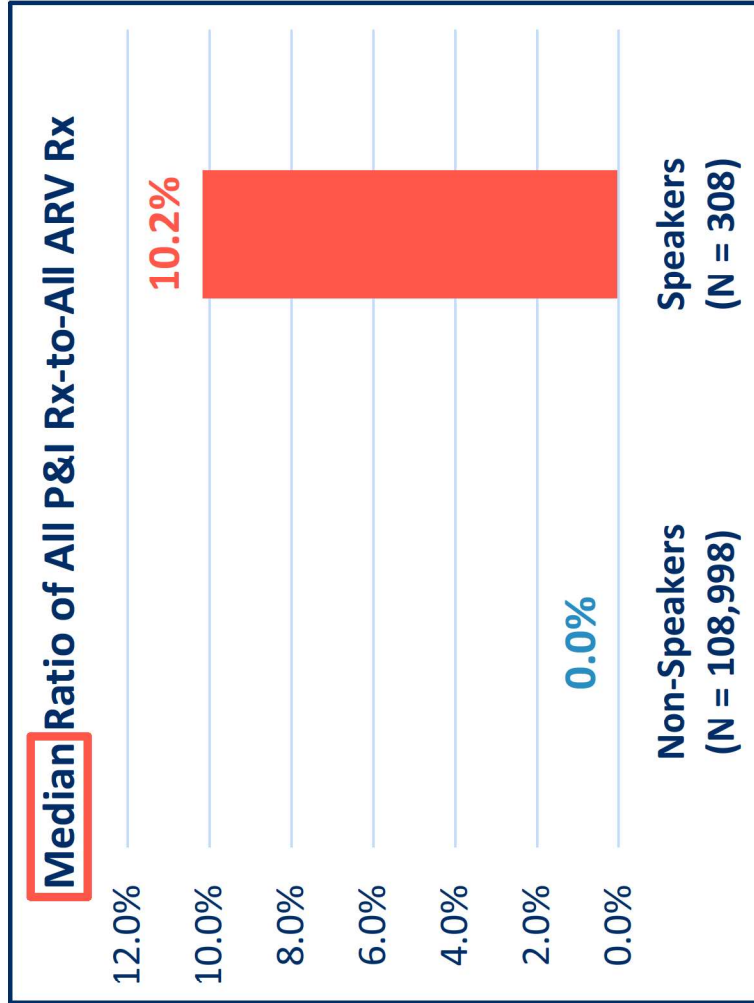


An average speaker prescribed 36 times (11.10%/0.31%) more P&I Rx than an average non-speaker.

Note: Analysis based on Medicare, Medicaid and ADAP data.
Source: Expert Report of Prof. Shaked, Analysis 3.

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

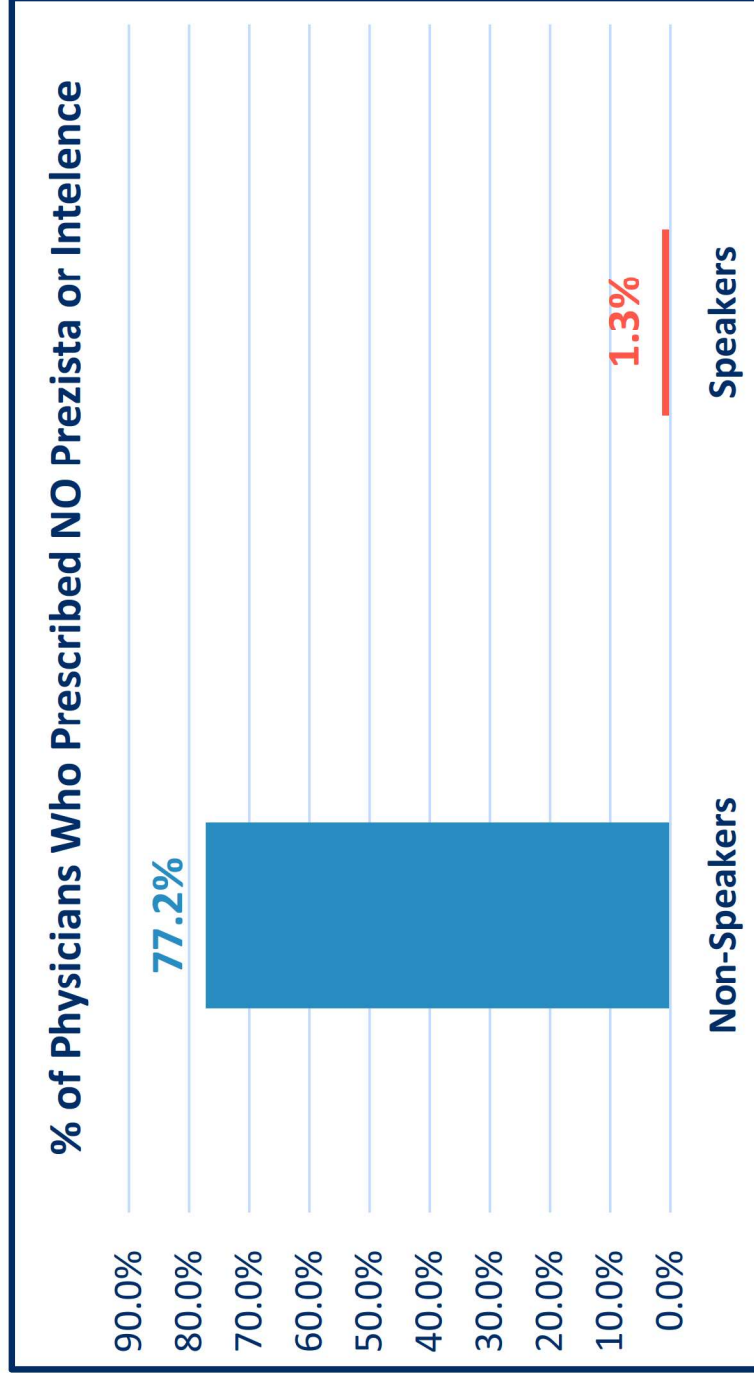
Speakers Were More Likely than Non-Speakers to Prescribe P&I



Note: All physicians analyzed prescribed at least one ARV drug from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 5.

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

Speakers Were More Likely than Non-Speakers to Prescribe P&I



Note: All physicians analyzed prescribed at least one ARV drug from 2006 to 2014 (Medicare).

Source: Expert Report of Prof. Shaked, Analysis 5.

Anti-Kickback Analyses: Speaker Disproportionate Level of P&I Rx

Speakers Were More Likely than Non-Speakers to Prescribe P&I

Test: Difference of Two Population Means

Ratio of All P&I Rx-to-All ARV Rx		
Statistic	Non-Speakers	Speakers
Number of Physicians	108,998	308
Median	0.0%	10.2%
Average	4.9%	10.4%

Z score = 21.48

The probability that the difference between averages happened by chance is less than 1 in 10 billion

Based on the strength of the results of the statistical test, Janssen speakers were more likely to prescribe P&I Rx than non-speakers.

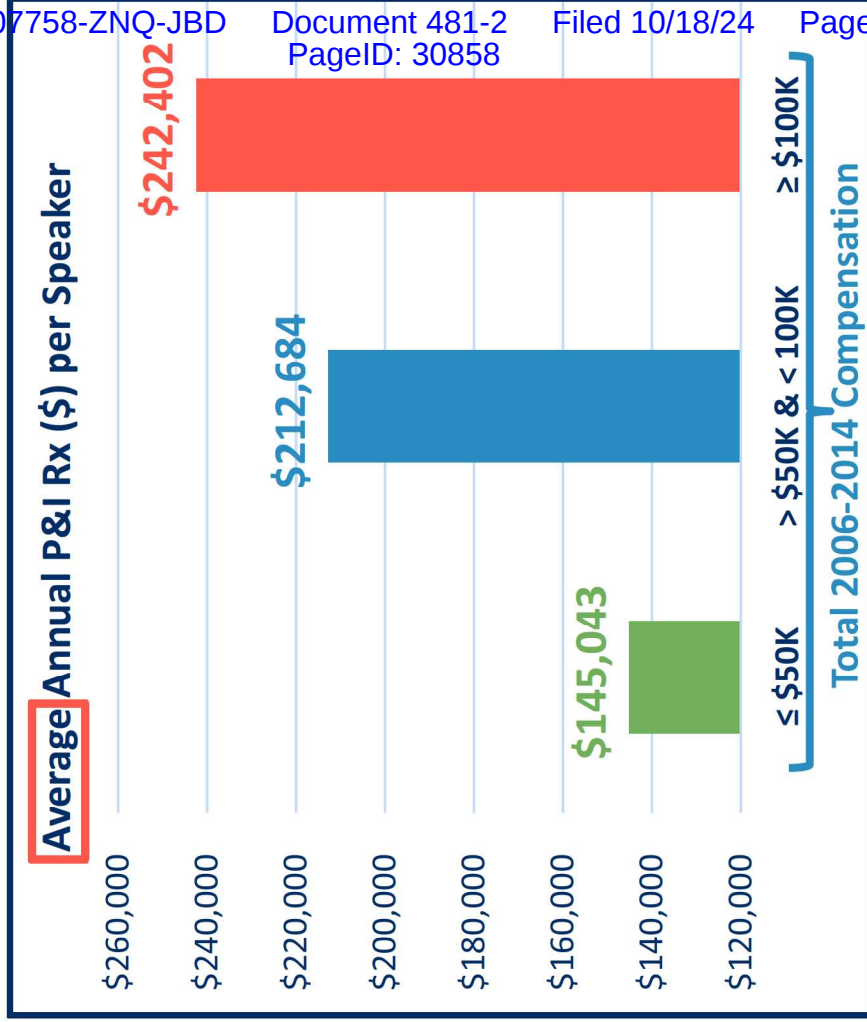
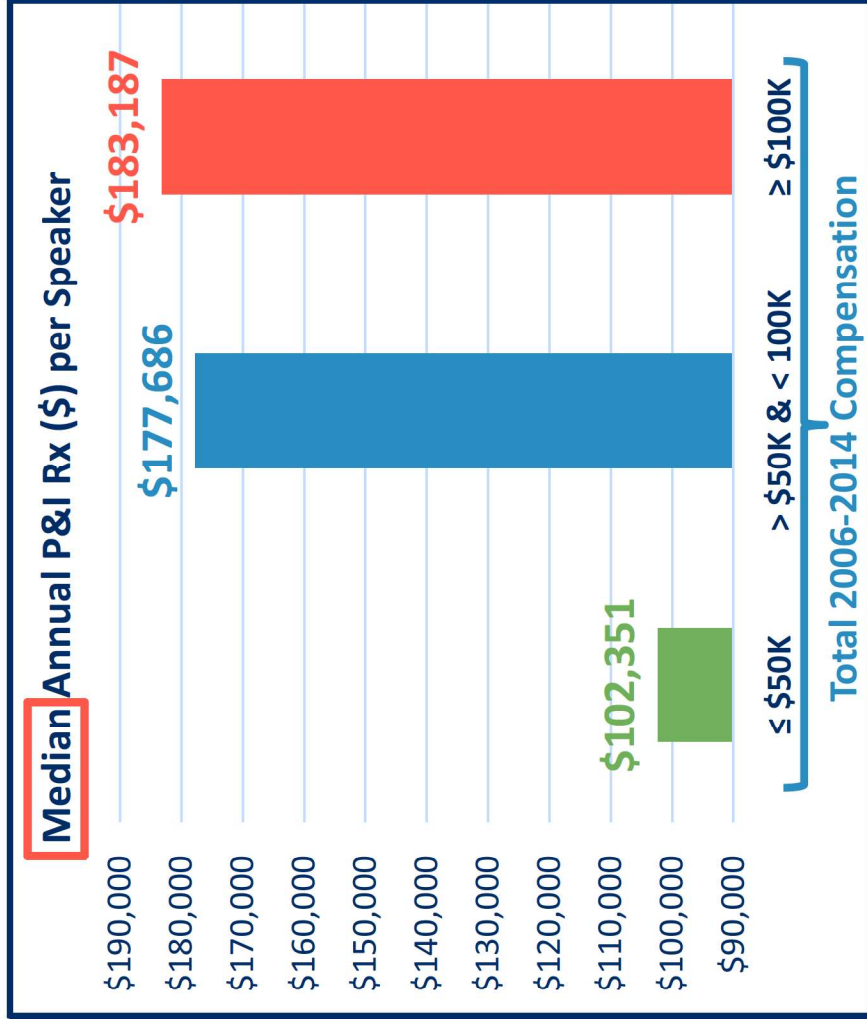
Note: Z score of 1.65 suggests statistical significance at the 95% confidence level.
All physicians analyzed prescribed at least one ARV drug from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 5.

Anti-Kickback Analyses: Speakers' Rx vs. Compensation

Anti-Kickback Analyses: Speakers' Rx vs. Compensation

Speakers Who Received More Compensation Prescribed More P&I Rx (\$) than Speakers Who Received Less Compensation

□ Grouping speakers by total 2006-2014 compensation:

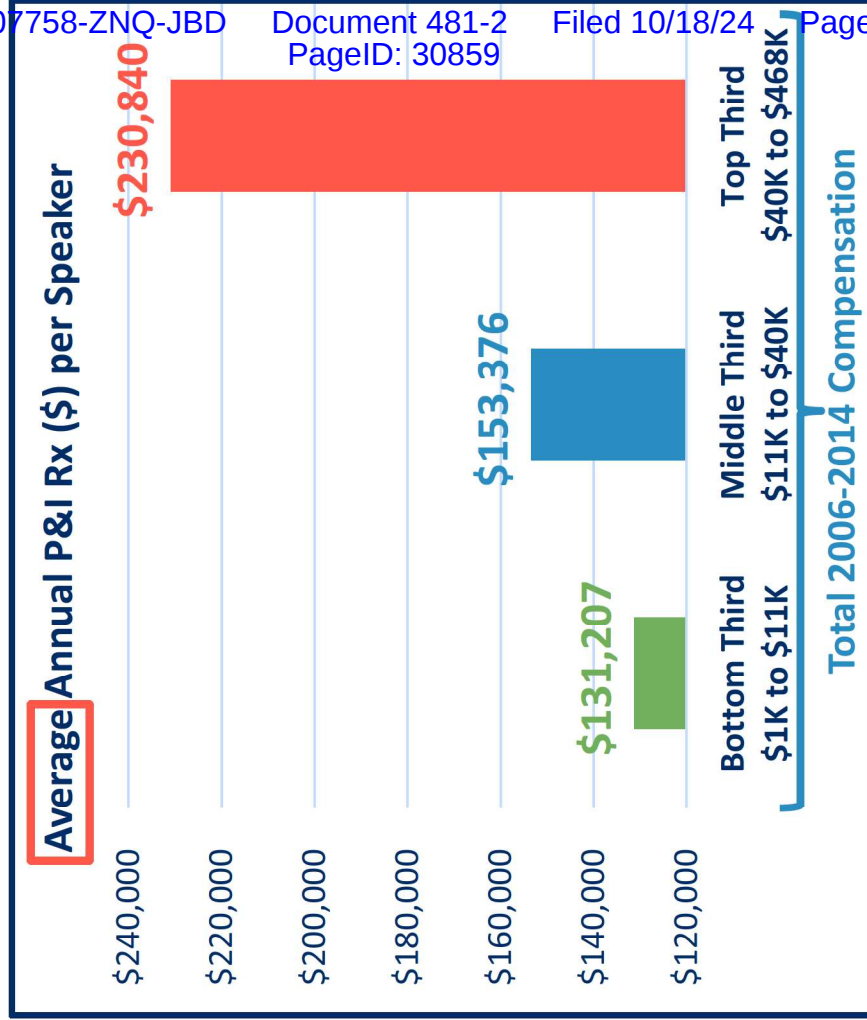
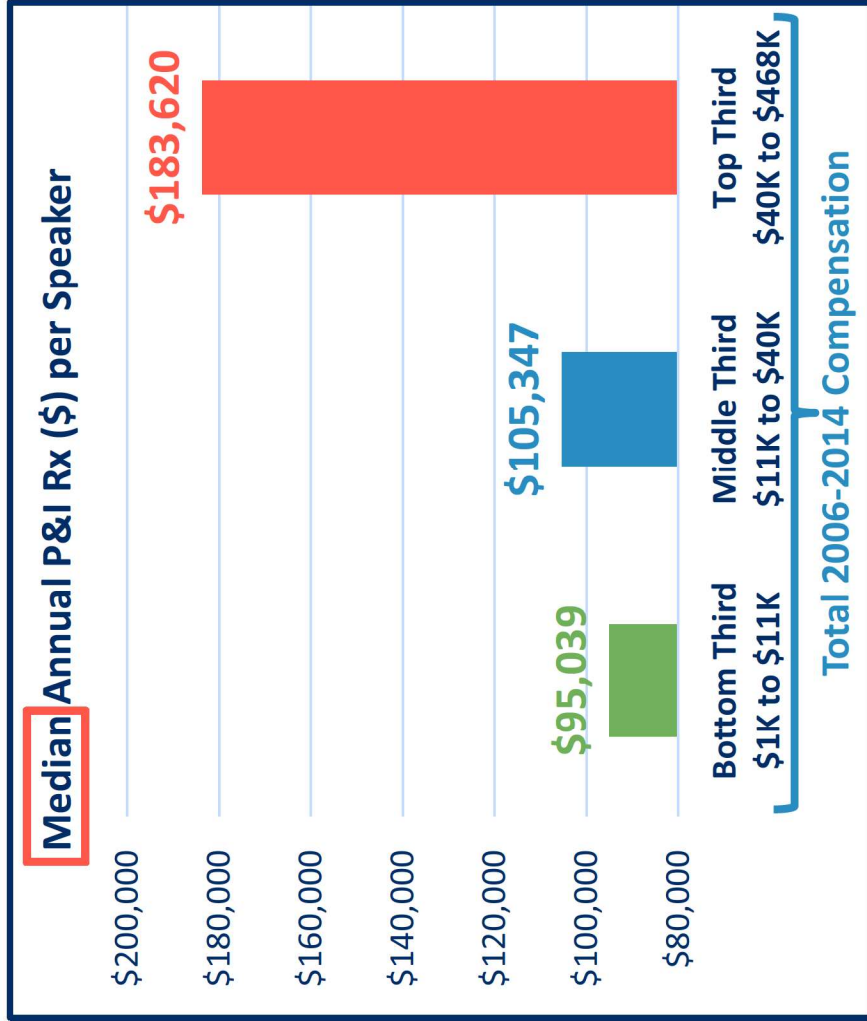


Note: The groups presented in the chart consist of the following number of physicians (from left to right): 207, 45, and 53. Analysis based on 305 speakers who had at least 1 P or I Rx from 2006 to 2014 and had a known NPI number (Medicare, Medicaid and ADAP). Total speaker compensation does not include speaker training fees and speaker expenses. Source: Expert Report of Prof. Shaked, Analysis 4A.

Anti-Kickback Analyses: Speakers' Rx vs. Compensation

Speakers Who Received More Compensation Prescribed More P&I Rx (\$) than Speakers Who Received Less Compensation

□ Dividing the speakers to 3 equal size groups based on total 2006-2014 compensation:



Note: The groups presented in the chart consist of the following number of physicians (from left to right): 101, 102, and 102. Analysis based on 305 speakers who had at least 1 P or I Rx from 2006 to 2014 and had a known NPI number (Medicare, Medicaid and ADAP). Total speaker compensation does not include speaker training fees and speaker expenses. Source: Expert Report of Prof. Shaked, Analysis 4A.

Anti-Kickback Analyses: Speakers' Rx vs. Compensation

Higher Speaker Compensation Linked to More P&I Rx (\$)

- ❑ I performed **Rank-Order Correlation Test**¹ to determine whether speakers who received more compensation prescribed more P&I Rx (\$) than speakers who received less compensation.

- ❑ Question: is the relationship positive and statistically significant?

- ❑ Calculating Rank-Order correlation between:

- 1) speaker rankings based on their total 2006-2014 compensation;
- 2) speaker rankings based on their annual average P&I Rx (\$).

Note: (1) Rank-Order correlation test is also referred to as Spearman's correlation test.
Analysis based on 305 speakers who had at least 1 P or I Rx from 2006 to 2014 and had a known NPI number (Medicare, Medicaid and ADAP).
Source: Expert Report of Prof. Shaked, Analysis 4B.

Anti-Kickback Analyses: Speakers' Rx vs. Compensation

Higher Speaker Compensation Linked to More P&I Rx (\$)

Rank-Order
Correlation
= 0.234

t-value
= 4.212

t-value of 4.2: Calculated correlation between speaker compensation and P&I Rx (\$) is statistically significant.

The statistical results indicate that speakers who received more compensation prescribed more P&I Rx (\$) than speakers who received less compensation.

Note: t-value of 1.65 suggests statistical significance at the 95% confidence level.

Analysis based on 305 speakers who had at least 1 P or I Rx from 2006 to 2014 and had a known NPI number (Medicare, Medicaid and ADAP).

Source: Expert Report of Prof. Shaked, Analysis 4B.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Comparison Groups:

Group 1

- Thousands of HIV Patients
- Get Prezista/Intelence
- Same Time Period
- Government Reimbursement
- **Thousands of Non-Influenced Physicians**

Group 2

- Thousands of HIV Patients
- Get Prezista/Intelence
- Same Time Period
- Government Reimbursement
- **Thousands of Influenced Physicians**

The primary difference between the two groups is that **influenced physicians** have received Janssen's Marketing, while the **non-influenced physicians** have not.

Influenced vs. Non-Influenced: Number of Initiated Patients

The Law of Large Numbers

	Prezista Patients	Intelence Patients	Total
Initiated by Influenced Physicians	55,879	20,111	75,990
Initiated by Non-Influenced Physicians	29,246	9,030	38,276
Total	85,125	29,141	114,266

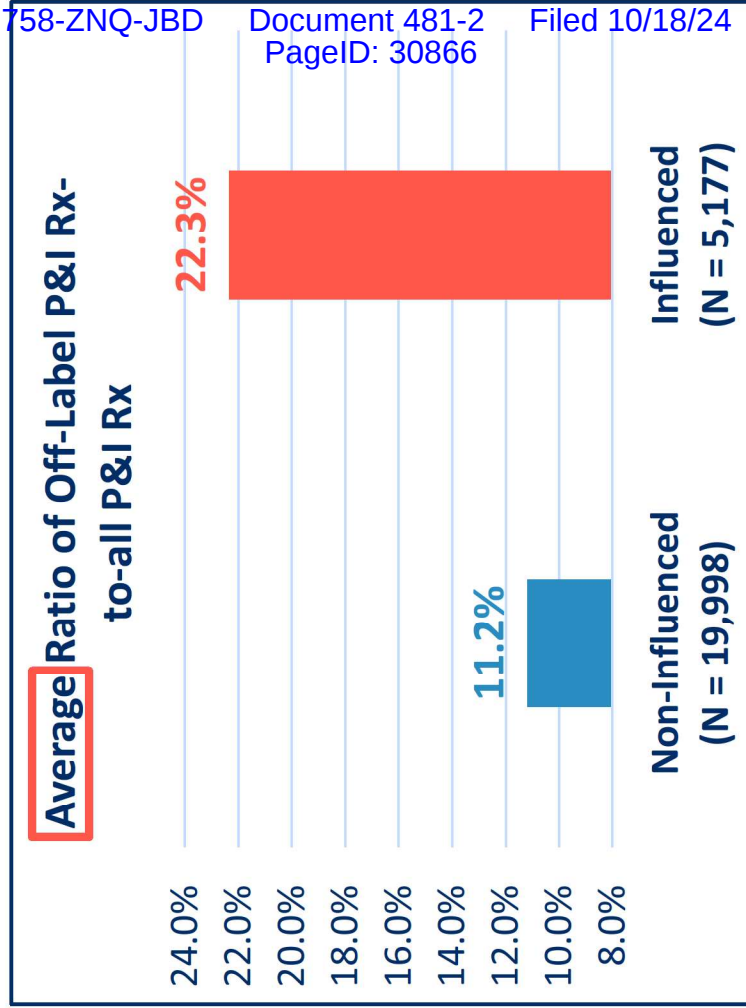
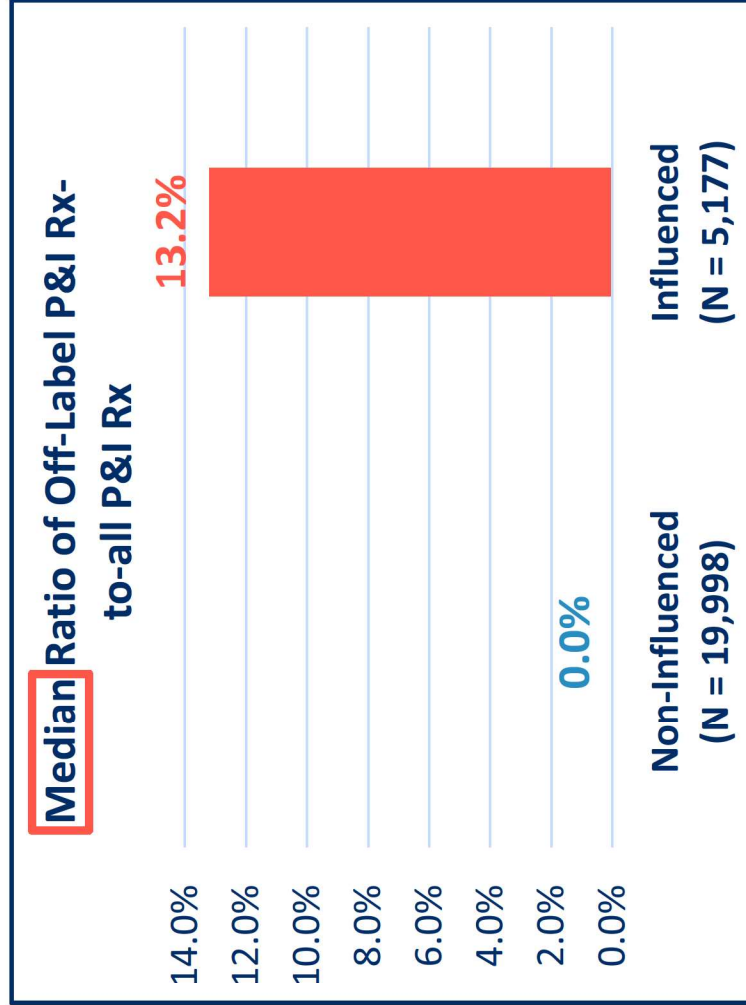
Note: Patient data for the period from 2006 to 2014 (Medicare and Medicaid). There are 6,012 influenced physicians who initiated at least 1 ARV patient and 48,443 non-influenced physicians who initiated at least 1 ARV patient. Source: Expert Supplemental Report of Prof. Shaked, Analysis 5.

Influenced Physicians are defined as physicians who either:

- Spoke at a Janssen speaking event;
- Attended a Janssen speaking event; or
- Received Janssen P&I Marketing.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Influenced Physicians Were More Likely to Prescribe P&I Off-Label than Non-Influenced Physicians



Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 6.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Influenced Physicians Were More Likely to Prescribe P&I Off-Label than Non-Influenced Physicians

Test: Difference of Two Population Means

Statistic	Ratio of Off-Label P&I Rx-to-all P&I Rx	
	Non-Influenced	Influenced
Number of Physicians	19,998	5,177
Median	0.0%	13.2%
Average	11.2%	22.3%

Z score = 26.46

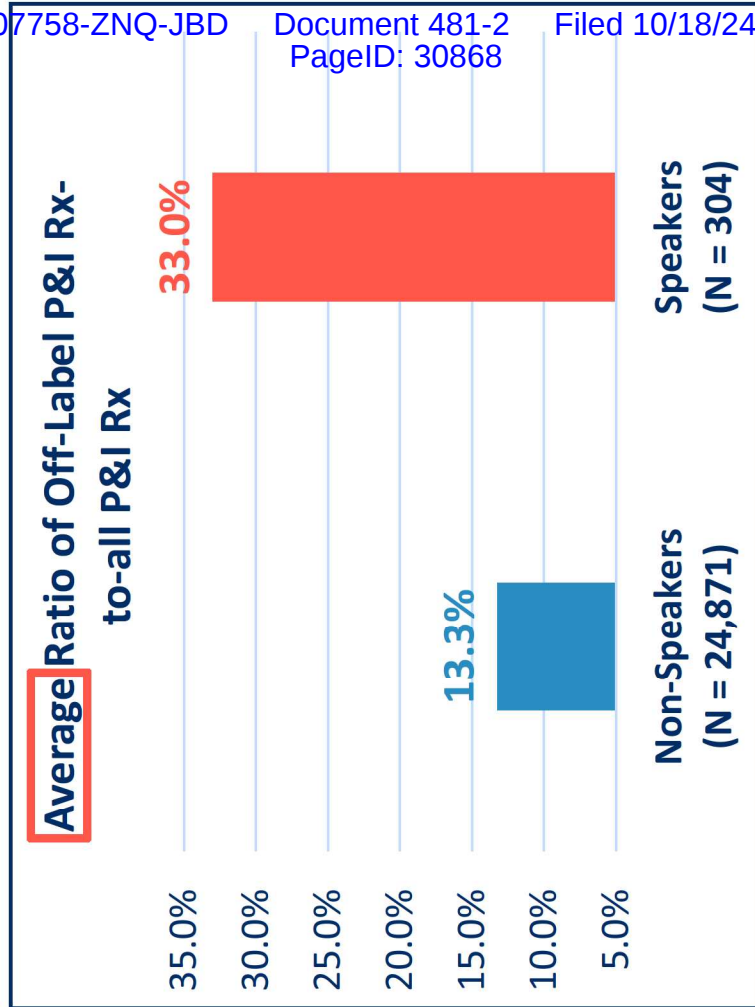
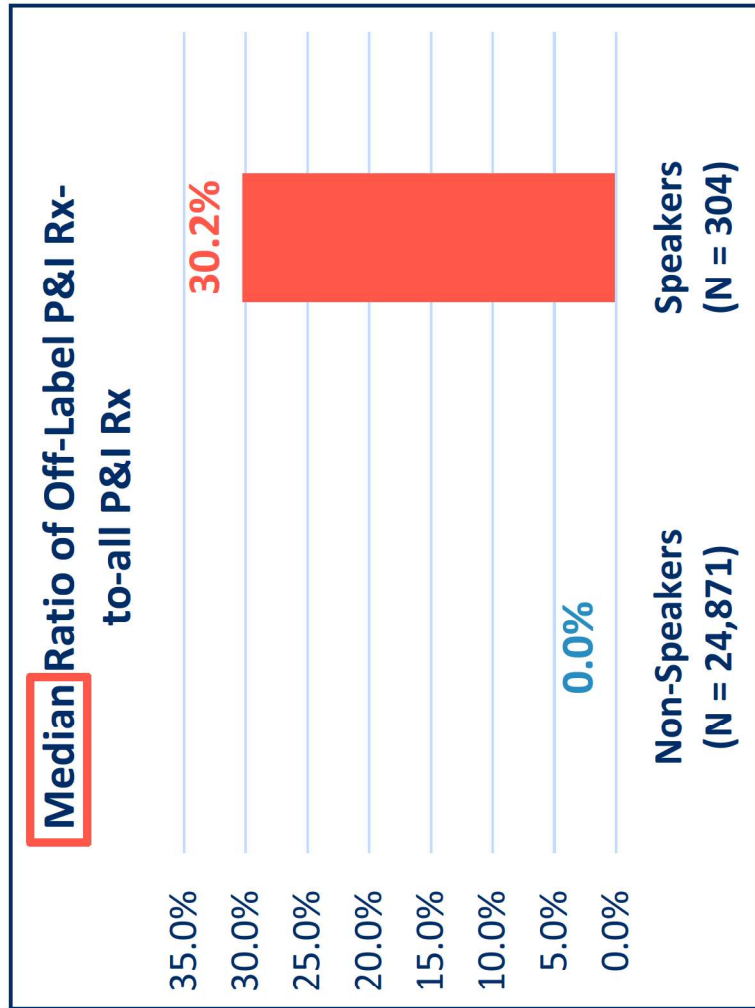
The probability that the difference between averages happened by chance is less than 1 in 10 billion

Based on the strength of the Z score, physicians influenced by Janssen off-label marketing were more likely to prescribe off-label P&I Rx than non-influenced physicians.

Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 6.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Speakers Were More Likely to Prescribe P&I Off-Label than Non-Speakers



Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 11.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Speakers Were More Likely to Prescribe P&I Off-Label than Non-Speakers

Test: Difference of Two Population Means

Statistic	Ratio of Off-Label P&I Rx-to-all P&I Rx	
	Non-Speakers	Speakers
Number of Physicians	24,871	304
Median	0.0%	30.2%
Average	13.3%	33.0%

Z score = 17.30

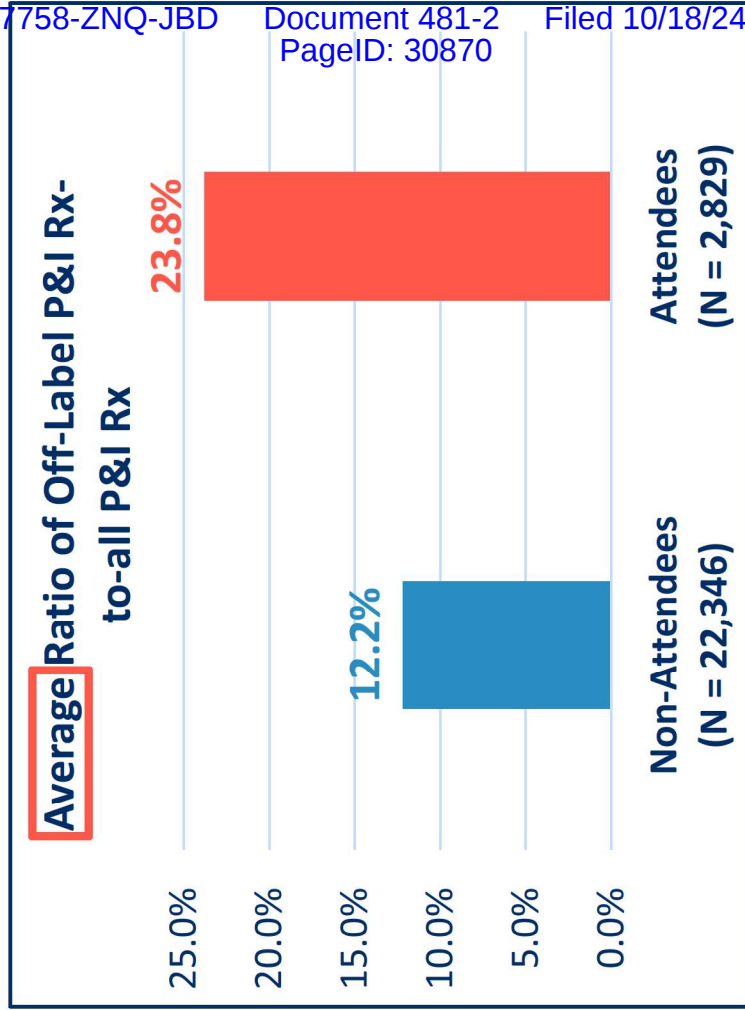
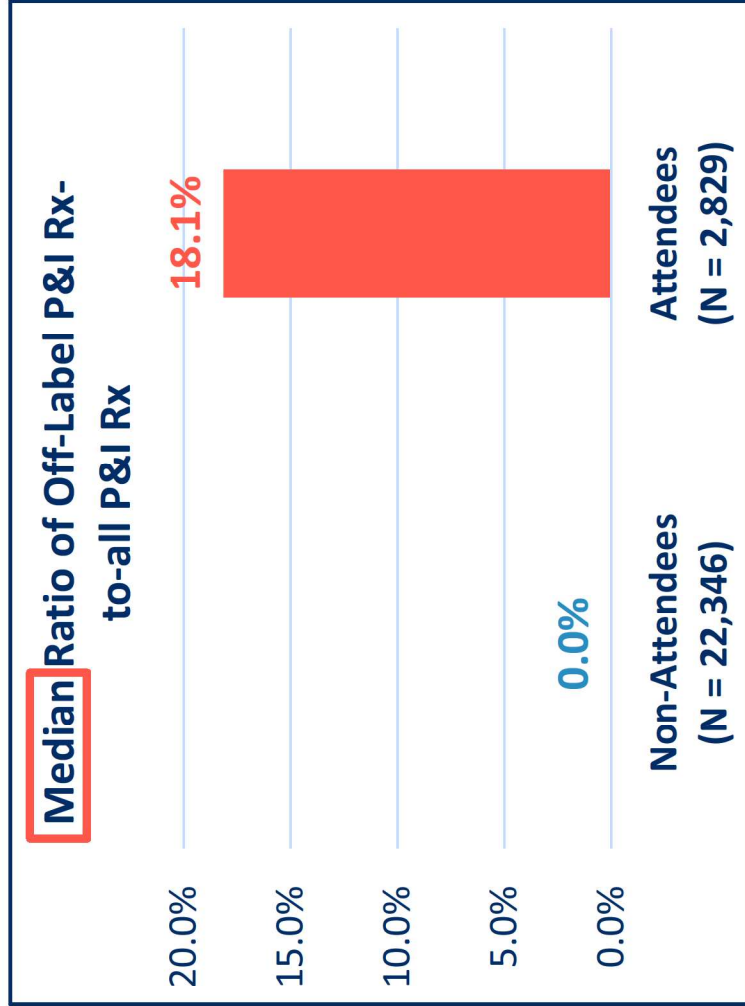
The probability that the difference between averages happened by chance is less than 1 in 10 billion

Based on the strength of the Z score, speakers were more likely to prescribe off-label P&I Rx than non-speakers.

Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 11.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Attendees Were More Likely to Prescribe P&I Off-Label than Non-Attendees



Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 9.

Off-Label Analyses: Comparisons of P&I Off-Label Rates

Speaker Event **Attendees** (**"Attendees"**) Were More Likely to Prescribe P&I Off-Label than Non-Attendees

Test: Difference of Two Population Means

Statistic	Ratio of Off-Label P&I Rx-to-all P&I Rx	
	Non-Attendees	Attendees
Number of Physicians	22,346	2,829
Median	0.0%	18.1%
Average	12.2%	23.8%

Z score = 22.27

The probability that the difference between averages happened by chance is less than 1 in 10 billion

Based on the strength of the Z score, attendees were more likely to prescribe off-label P&I Rx than non-attendees.

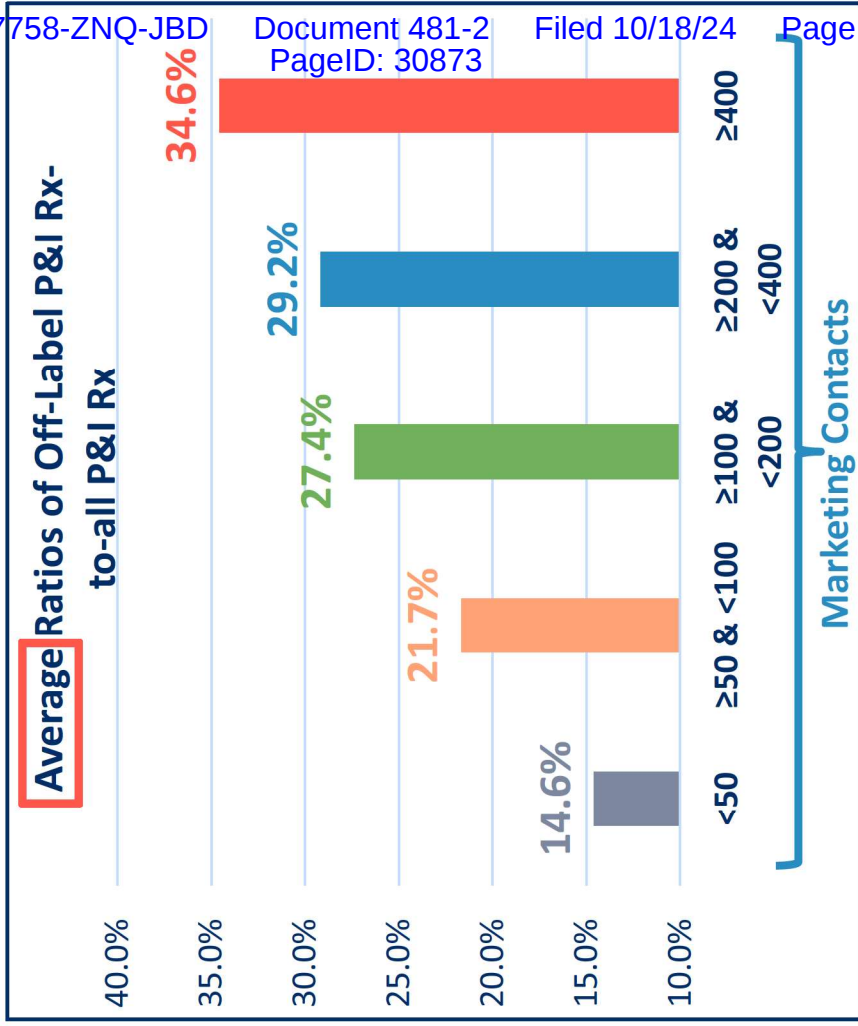
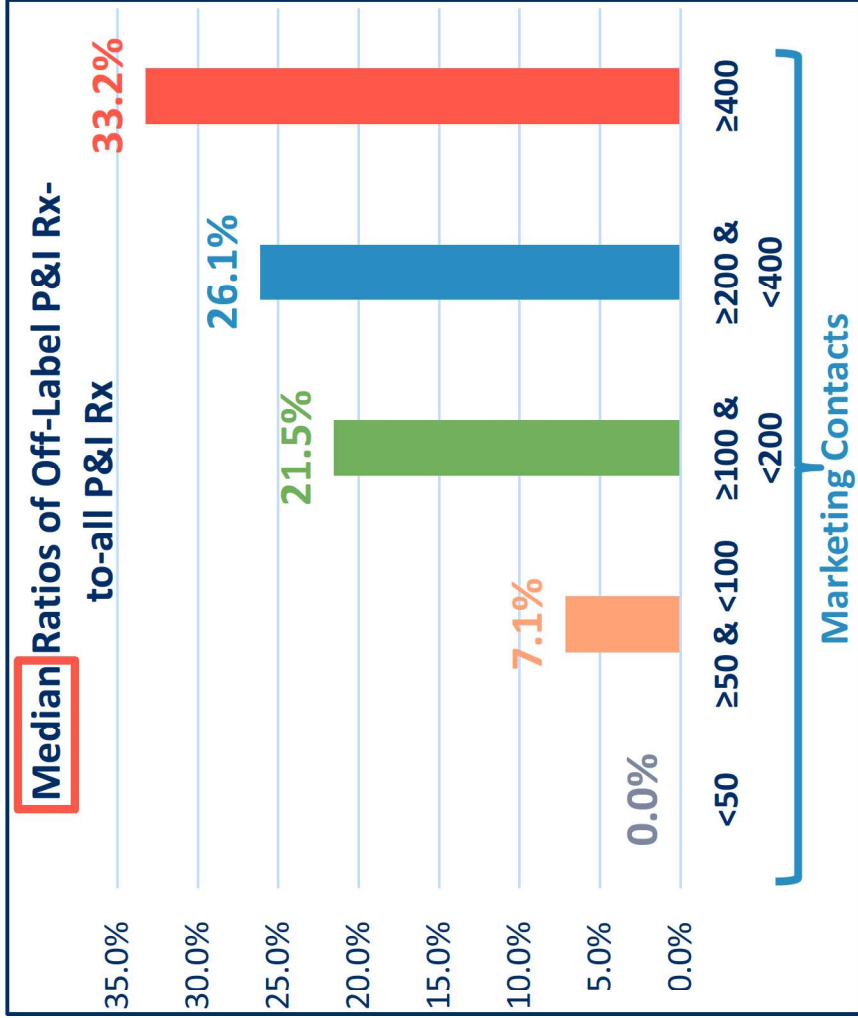
Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 9.

Off-Label Analyses: Marketing Contacts vs. P&I Off-Label Rates

Off-Label Analyses: Marketing Contacts vs. P&I Off-Label Rates

Physicians Who Received More Janssen Marketing Contacts Prescribed More Off-Label P&I Rx

- Grouping influenced physicians by the # of received Janssen marketing contacts: # of times a physician has spoken at or attended a speaking event, or received a marketing call from Janssen



Note: The groups presented in the chart consist of the following number of physicians (from left to right): 1,990, 832, 1,147, 848, and 360.

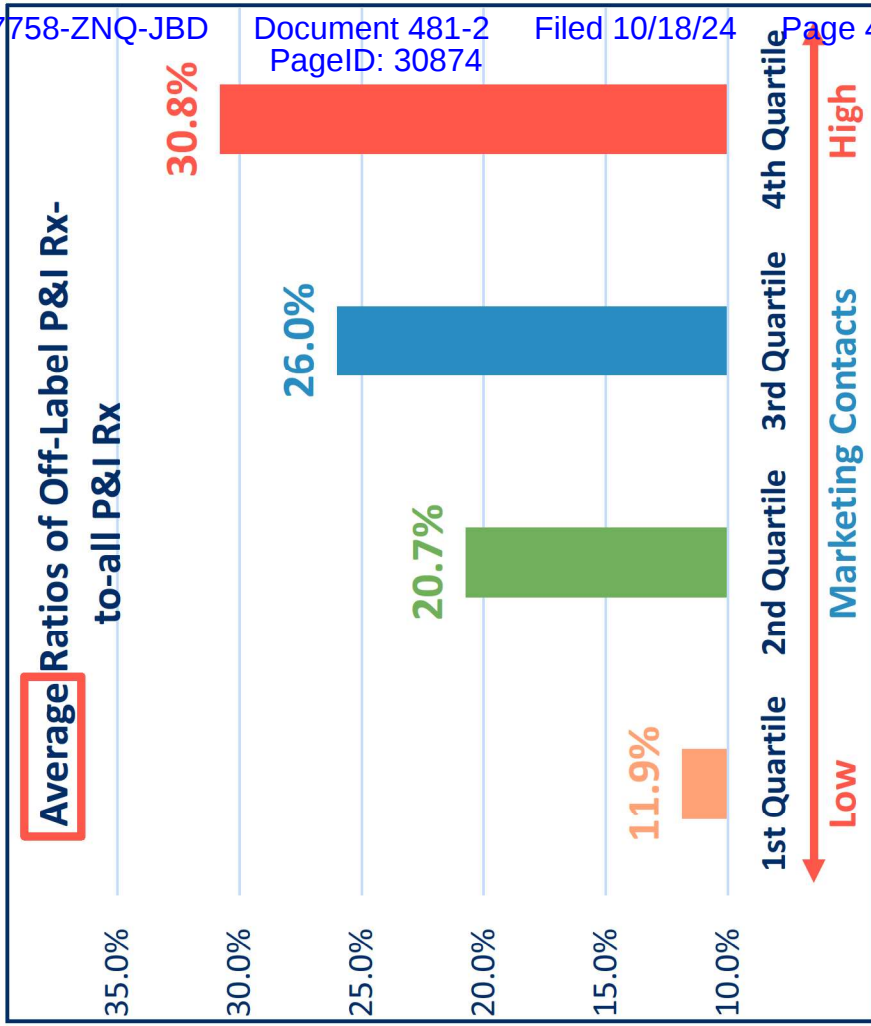
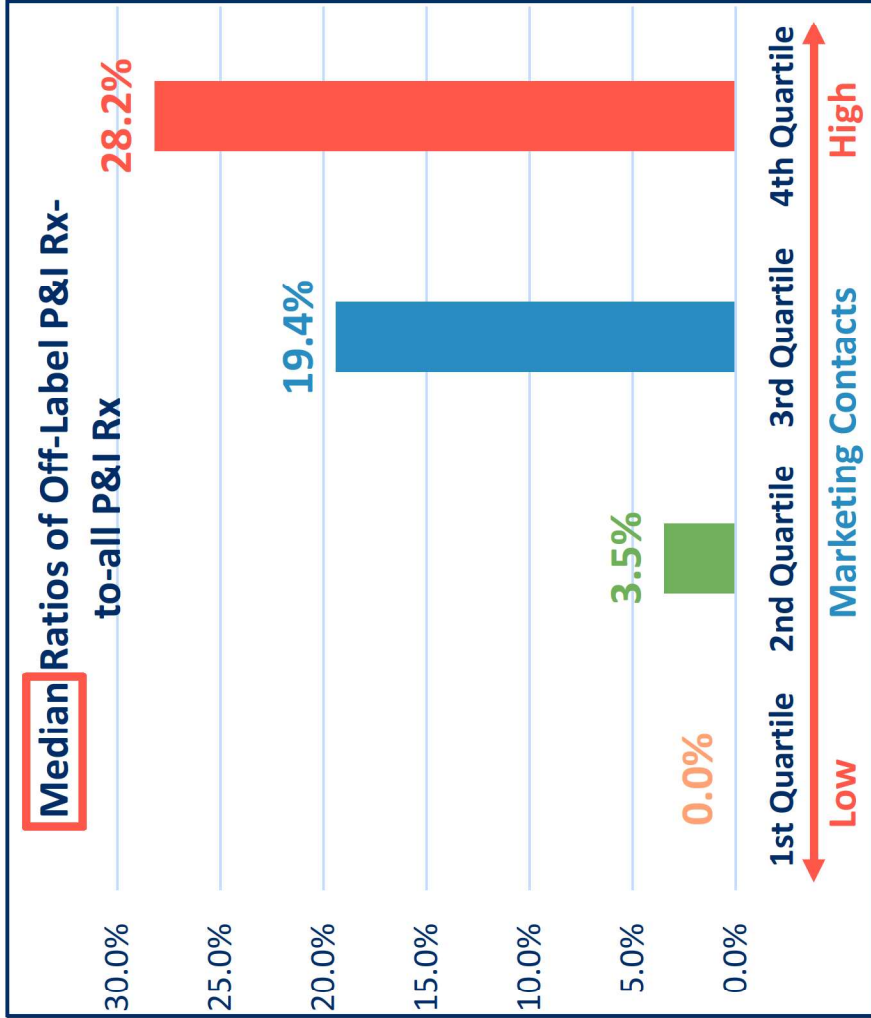
All analyzed influenced physicians prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).

Source: Expert Report of Prof. Shaked, Analysis 7A.

Off-Label Analyses: Marketing Contacts vs. P&I Off-Label Rx Rates

Physicians Who Received More Janssen Marketing Contacts Prescribed More Off-Label P&I Rx

- Dividing influenced physicians to 4 equal size groups based on the # of received Janssen marketing contacts:



Note: The groups presented in the chart consist of the following number of physicians (from left to right): 1,295, 1,294, 1,294, and 1,294. All analyzed influenced physicians prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare). Source: Expert Report of Prof. Shaked, Analysis 7A.

Off-Label Analyses: Marketing Contacts vs. P&I Off-Label Rates

Receiving More Marketing Contacts Is Linked to Higher P&I Off-Label Rates

- ❑ I performed **Rank-Order correlation test** to determine whether groups of influenced physicians who received more marketing contacts from Janssen prescribed more off-label P&I Rx than groups of physicians who received less marketing contacts.

➤ Calculating Rank-Order correlation between physician rankings based on:

- 1) Total received Janssen marketing contacts;
- 2) Ratio of off-label P&I Rx-to-all P&I Rx.

*Note: All analyzed influenced physicians prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 7B.*

Off-Label Analyses: Marketing Contacts vs. P&I Off-Label Rates

Receiving More Marketing Contacts Is Linked to Higher P&I Off-Label Rates

Rank-Order
Correlation
= 0.406

t-value
= 31.944

High t-value of over 31.9 shows that the calculated correlation between marketing contacts and the ratio of off-label P&I Rx-to-all P&I Rx is statistically significant.

Rank-Order correlation results indicate that physicians who received more marketing contacts from Janssen prescribed more off-label P&I Rx than physicians who received less marketing contacts from Janssen.

*Note: t-value of 1.65 suggests statistical significance at the 95% confidence level.
All analyzed influenced physicians prescribed at least 1 P or 1 Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 7B.*

Off-Label Analyses: Speakers' Off-Label P&I Rx

Off-Label Analyses: Speakers Off-Label P&I Rx

Speakers Wrote Over 20% of All Off-Label P&I Rx, While Accounting for 1.21% of All Physicians

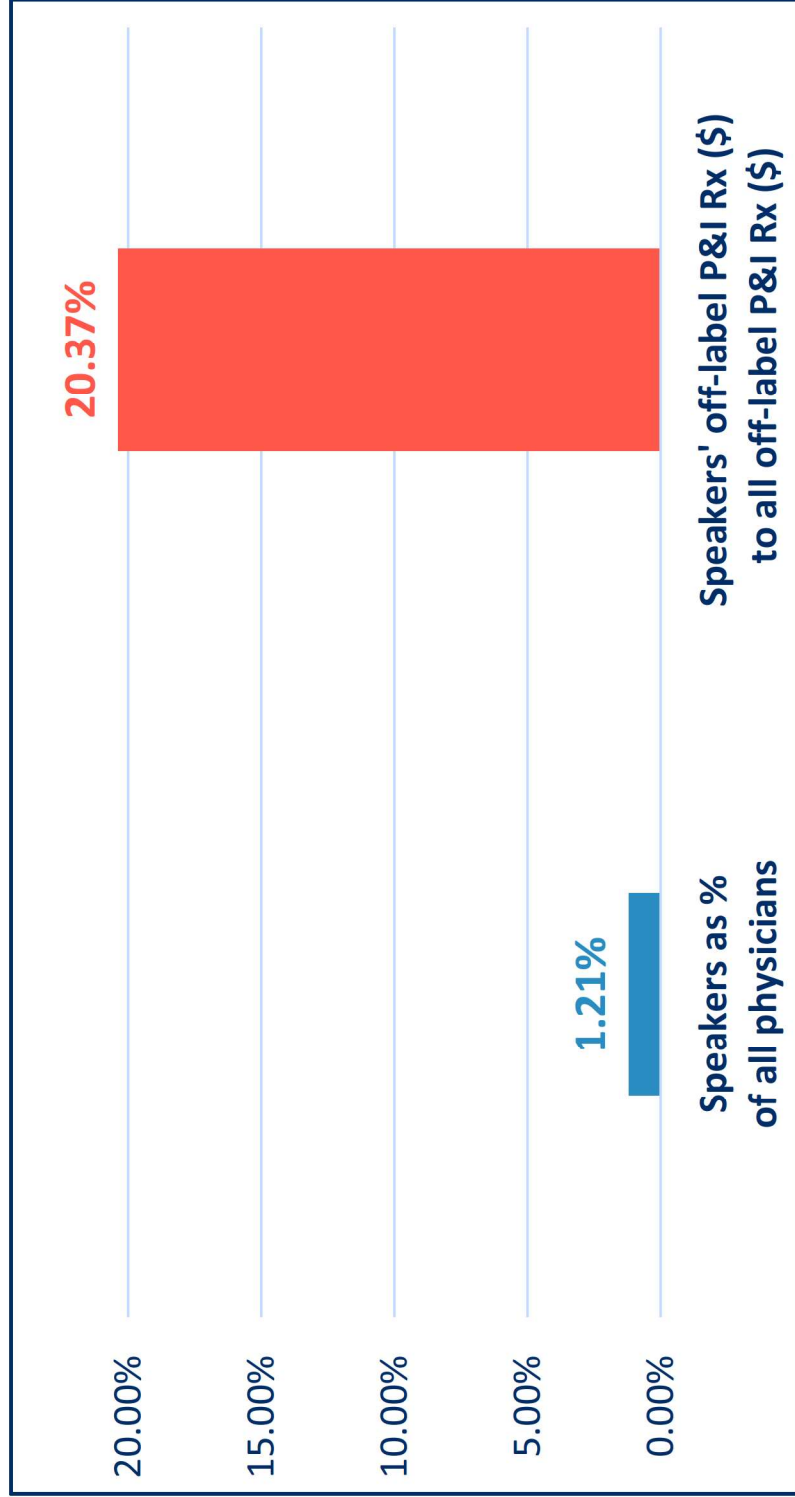
		Off-Label P&I Rx (\$)	
		# of Physicians	Reimbursed by Medicare
Speakers		304	\$ 71,053,476
All Physicians		25,136	\$ 348,782,616
Speakers as a % of Total		1.21%	20.37%

An average speaker prescribed almost 17 (20.37%/1.21%) times more off-label P&I Rx than an average non-speaker.

Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 12.

Off-Label Analyses: Speakers Off-Label P&I Rx

Speakers Wrote Over 20% of All Off-Label P&I Rx, While Accounting for 1.21% of All Physicians

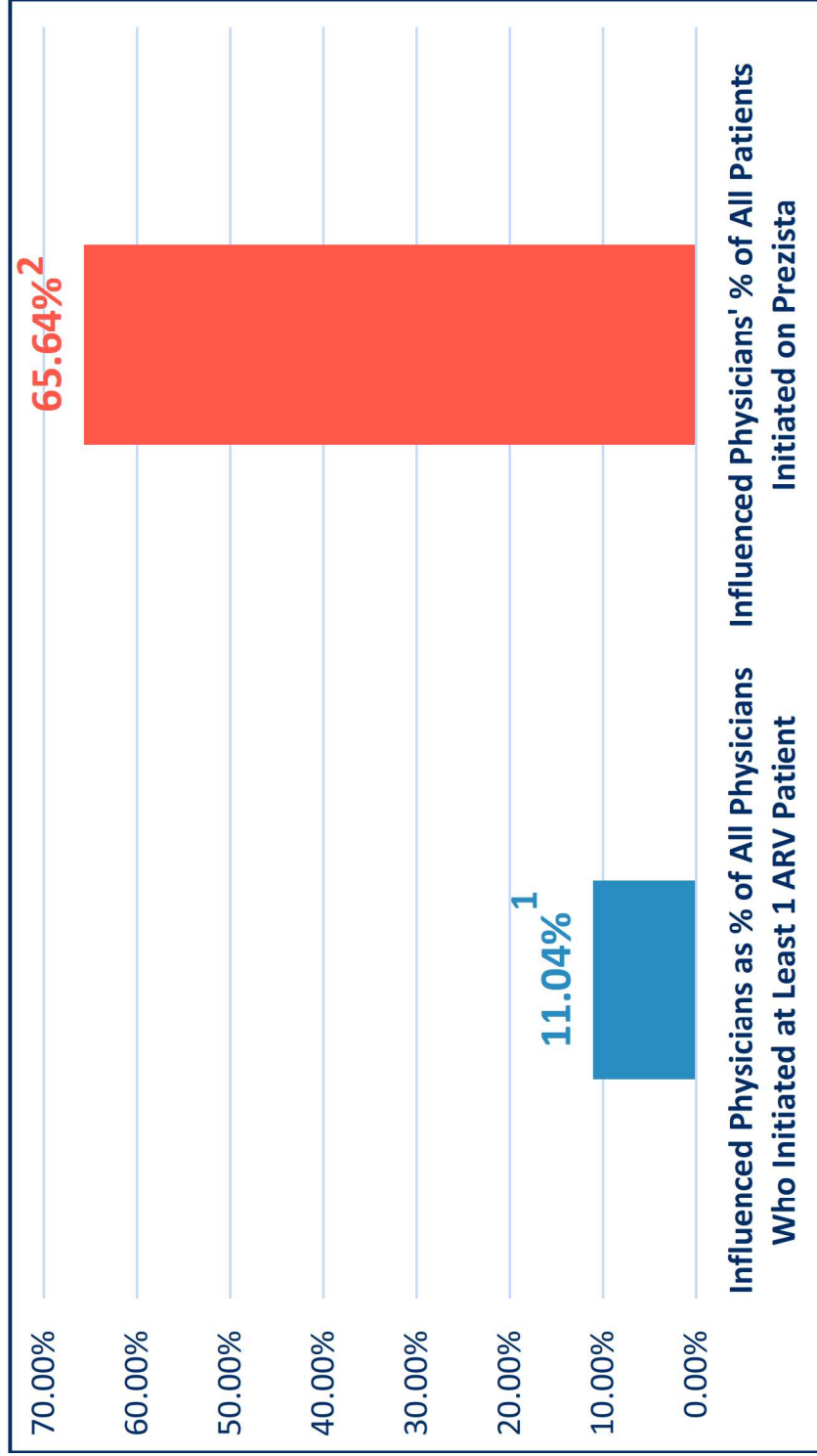


Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 12.

Comparing Groups of Physicians Who Initiated at Least 1 ARV Patient

Comparing Groups of Physicians Who Initiated at Least 1 ARV Patient

Influenced Physicians Initiated Over 65% of Patients on **Prezista**



Note: All physicians have initiated at least 1 ARV patient from 2006 to 2014 (Medicare and Medicaid).

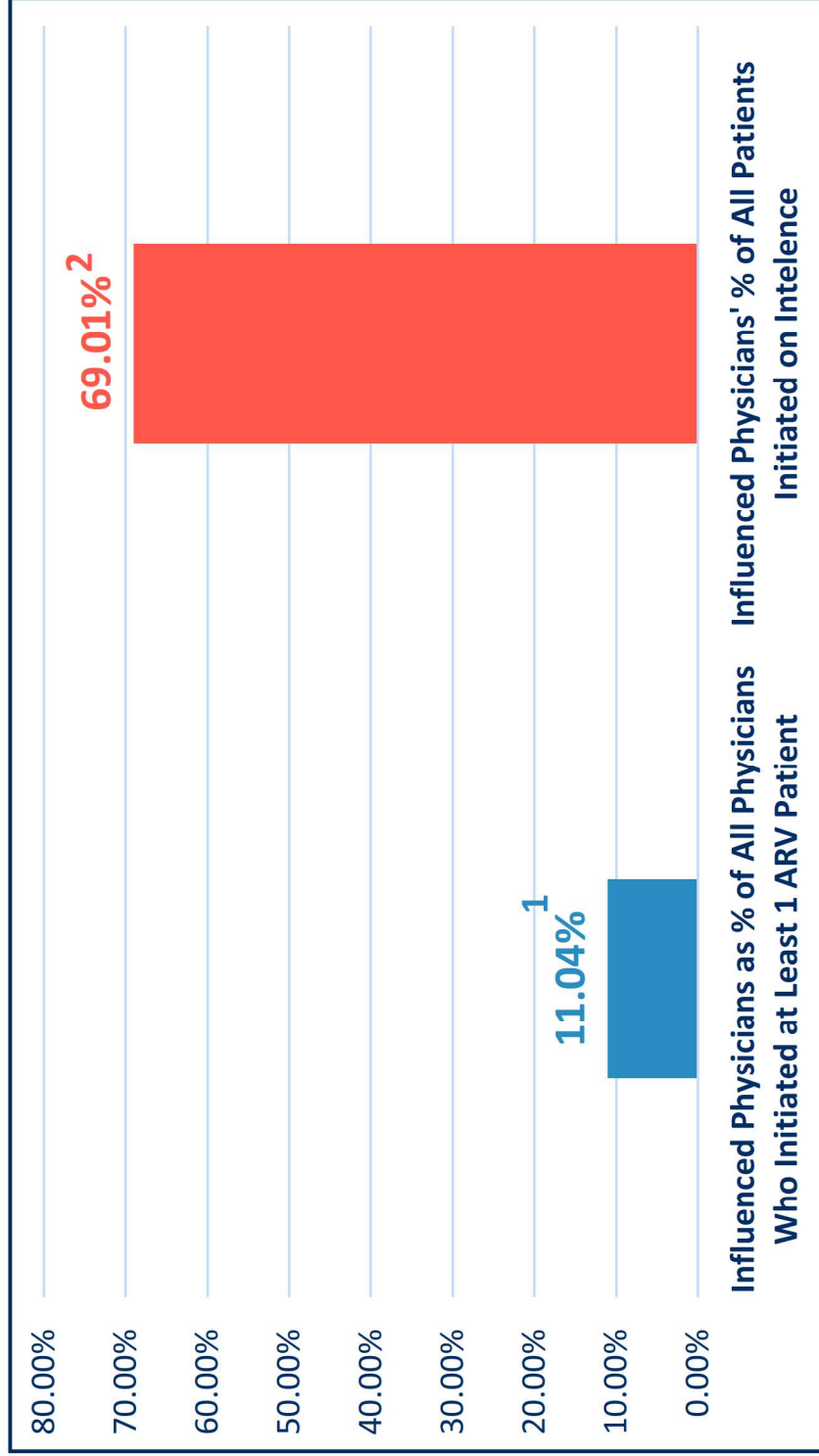
(1) influenced physicians / all physicians who initiated at least 1 ARV patient = 6,012 / 54,455 = 11.04%

(2) influenced physicians' # of Prezista patients initiated / all physicians' # of Prezista patients initiated = 55,879 / 85,125 = 65.64%

Source: Expert Supplemental Report of Prof. Shaked, Analysis 5.

Comparing Groups of Physicians Who Initiated at Least 1 ARV Patient

Influenced Physicians Initiated Over 69% of Patients on **Intelle**



Note: All physicians have initiated at least 1 ARV patient from 2006 to 2014 (Medicare and Medicaid).

(1) influenced physicians / all physicians who initiated at least 1 ARV patient = 6,012 / 54,455 = 11.04%

(2) influenced physicians' # of Intelle patients initiated / all physicians' # of Intelle patients initiated = 20,111 / 29,141 = 69.01%

Source: Expert Supplemental Report of Prof. Shaked, Analysis 5.

Janssen's Incorrect Statements Regarding Its Own Marketing

Janssen's Incorrect Statements Regarding Its Own Marketing

Janssen's Expert incorrectly claims that Janssen's marketing may not affect physicians' prescribing behavior.

Response:

Marketing Contacts	# of Influenced Physicians	% of Influenced Physicians (5,177)
1	328	6.3%
2 - 10	737	14.2%
11 - 50	941	18.2%
51 - 100	823	15.9%
101 - 200	1,150	22.2%
201 - 300	554	10.7%
301 - 400	284	5.5%
401 - 500	160	3.1%
501 - 600	92	1.8%
601 - 700	47	0.9%
701 - 800	28	0.5%
801 - 900	15	0.3%
901 +	18	0.3%

Marketing Contacts	# of Influenced Physicians	% of Influenced Physicians (5,177)
1 +	5,177	100.0%
5 +	4,439	85.7%
10 +	4,157	80.3%
25 +	3,680	71.1%
50 +	3,187	61.6%
100 +	2,355	45.5%
200 +	1,208	23.3%
250 +	876	16.9%
300 +	644	12.4%
350 +	491	9.5%
400 +	360	7.0%
500 +	201	3.9%
1000 +	10	0.2%

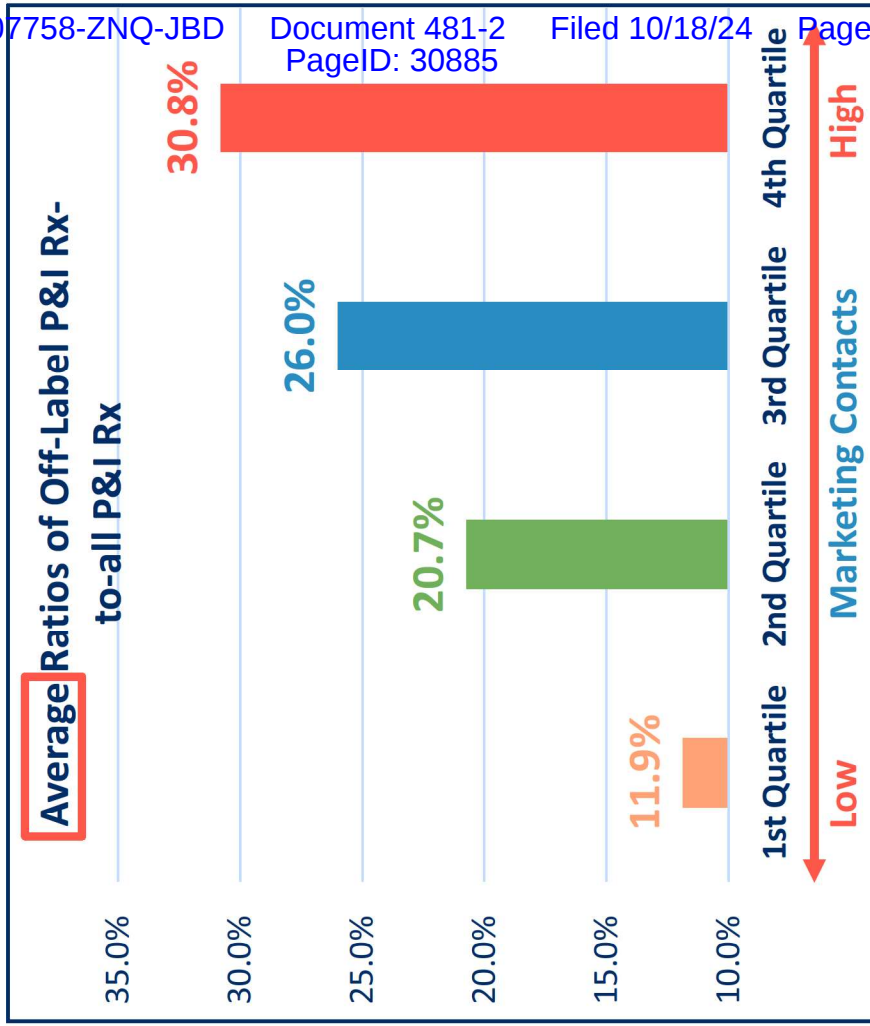
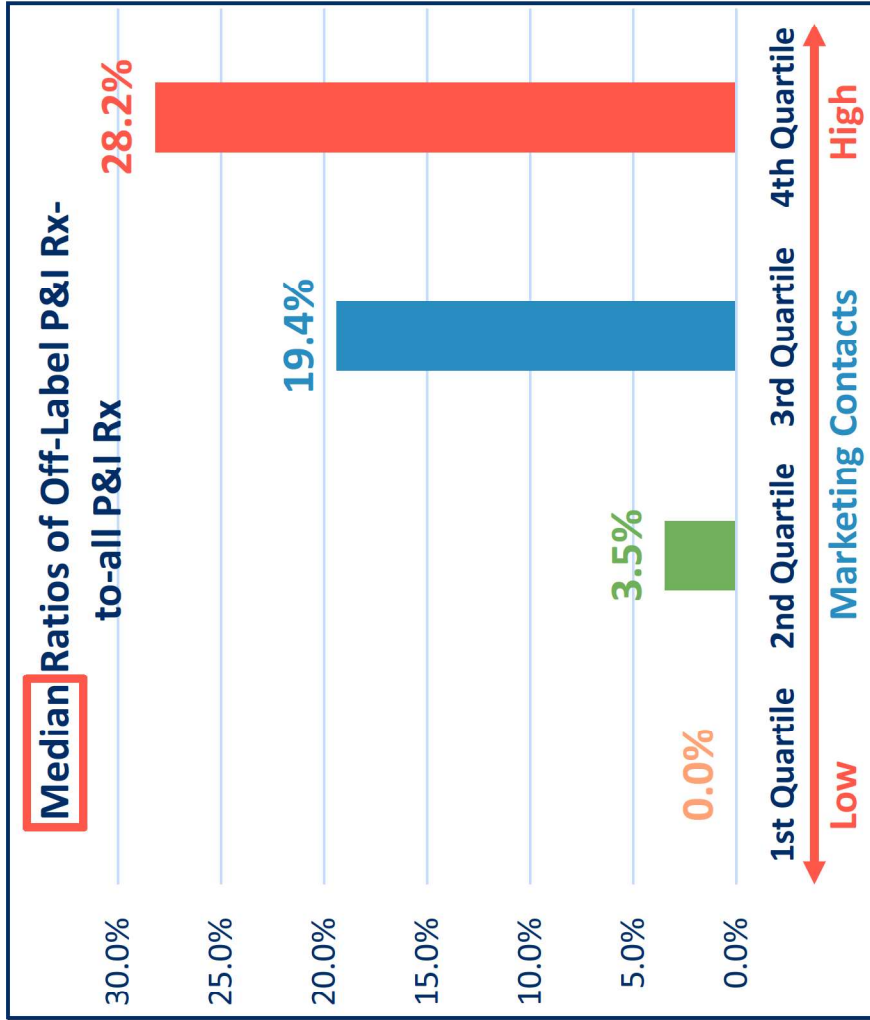
Median # of Janssen Marketing Contacts: 85
Average # of Janssen Marketing Contacts: 135

Note: All physicians analyzed prescribed at least 1 P or 1 Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Exhibit 26.

Janssen's Incorrect Statements Regarding Its Own Marketing

Response (continued):

- Dividing influenced physicians to 4 equal size groups based on the # of received Janssen marketing contacts:

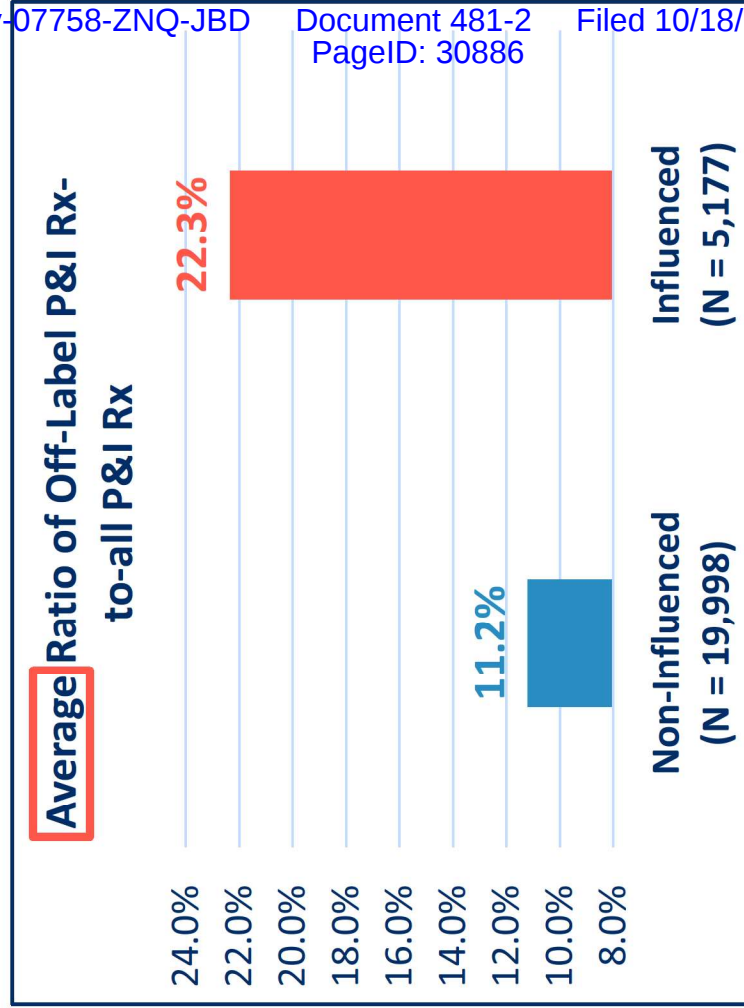
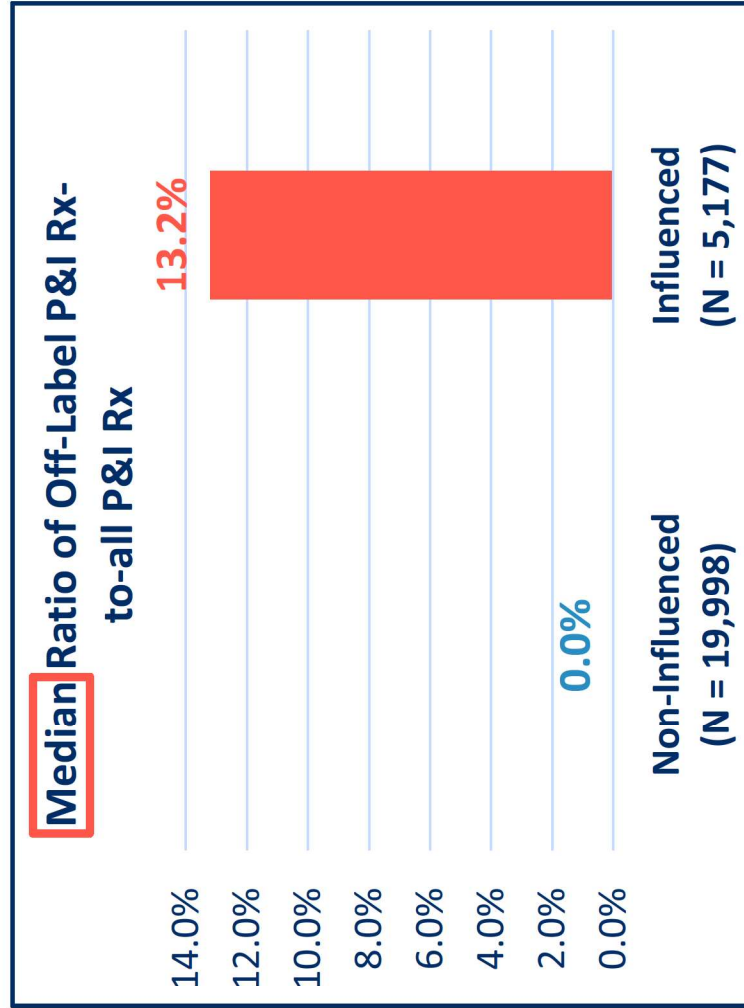


Note: The groups presented in the chart consist of the following number of physicians (from left to right): 1,295, 1,294, 1,294, and 1,294.
 All analyzed influenced physicians prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).

Source: Expert Report of Prof. Shaked, Analysis 7A.

Janssen's Incorrect Statements Regarding Its Own Marketing

Response (continued):



Note: All physicians analyzed prescribed at least 1 P or I Rx from 2006 to 2014 (Medicare).
Source: Expert Report of Prof. Shaked, Analysis 6.

PILM's Return-on-Investment Analysis of Janssen's Marketing

PILM's Return-on-Investment Analysis of Janssen's Marketing

- ☐ Partners In Loyalty Marketing ("PILM") is a marketing consulting firm which analyzes return on investments ("ROI") for marketing programs in various industries.
- ☐ Janssen hired PILM, an unrelated third party, to conduct an evaluation of the effectiveness of its marketing initiatives, including Speaker Programs and the Sales Force.

Screenshot from PILM Report:¹

- PILM evaluates the number of prescribing vs. non-prescribing physicians in pre and post program periods to help answer:
 - ✓ Do new physicians start to write post program exposure?
 - ✓ Are current prescribers continuing to write (or write more) post program exposure?

(1) Partners in Loyalty Marketing Inc, "PILM Capabilities: Measuring ROI for Janssen," November 17, 2011, p. 7.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Janssen's Finance & Marketing Department Approved PILM's Analysis Models

Screenshot from PILM Report:

- ▶ All PILM scorecards use a straight forward P&L model that incorporates
 - ✓ Incremental prescriptions, and sales, against costs to calculate true ROI
 - ✓ A transparent model that has been approved by Janssen's finance and marketing departments

Source: Partners in Loyalty Marketing Inc, "2011 Program Evaluations Measuring ROI," April 20, 2012, p. 4.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Janssen's Speaker Program Results (January – November 2011)

Screenshot from PILM Report:

Medforce (Thru Nov '11)	Actual
Investment	\$2,655,569
Participants	11,859
Medforce	7,323
Unbranded Disease Awareness	4,536
Breakeven TRx	3,849
Evaluated YTD (Match IMS ID#)	
Participants	1,095
TRx Lift / Participant	5.35
Total TRx Lift	5,857
Total NTS Lift	\$4,041,513
Bottom Line ROI	\$0.52
Estimated YTD (Total Participants – Weighted Lift)	
TRx Lift / Participant	0.94
Total TRx Lift	11,174
Total NTS Lift	\$7,709,853
BL ROI (\$X: \$1)	\$2.90

Investment

Total Rx Lift
per Participant

NTS = Net Trade Sales
(Incremental Sales)

Each dollar invested
in the speaker
program returned
\$2.90.

$$\frac{\$7,709,853}{\$2,655,569} = \$2.90$$

Source: Partners in Loyalty Marketing Inc, "2011 Program Evaluations Measuring ROI," April 20, 2012, p. 23.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Janssen's Speaker Program Results (January – November 2012)

Screenshot from PILM Report:

Medforce Branded Speaker Programs	Jan - Nov
Investment	\$1,381,906
Participants	4,240
Breakeven TRx	2,003
Actual Matched YTD (IMS ID#)	
Participants	611
TRx Lift / Participant	5.55
Total TRx Lift	3,394
Total NTS Lift	\$2,341,871
Bottom Line ROI	\$1.69
Extrapolated Total (Total Participants – 14%* evaluated lift applied to non-matched participants)	
TRx Lift / Participant	1.49
Total TRx Lift	6,299
Total NTS Lift	\$4,346,270
BL ROI (\$X: \$1)	\$3.15

Investment

Total Rx Lift
per Participant

Incremental
Sales

Each dollar invested
in the speaker
program returned
\$3.15.

$$\frac{\$4,346,270}{\$1,381,906} = \$3.15$$

Source: Partners in Loyalty Marketing Inc, "2012 Program Evaluations Measuring ROI," January 22, 2013, p. 23.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Janssen's Speaker Program Results (Q1 – 2013)

Screenshot from PILM Report:

Medforce Branded Speaker Programs	Q1 2013
Investment	\$79,056
Participants	310
Breakeven TRx	105
Actual Matched YTD (IMS ID#)	
Participants	67
TRx Lift / Participant	2.50
Total TRx Lift	167
Total NTS Lift	\$125,975
Bottom Line ROI	\$1.59
Extrapolated Total (Total Participants – 22%* evaluated lift applied to non-matched participants)	
TRx Lift / Participant	0.96
Total TRx Lift	299
Total NTS Lift	\$224,723
BL ROI (\$X: \$1)	\$2.84

Investment

Total Rx Lift
per Participant

Incremental
Sales

Each dollar invested
in the speaker
program returned
\$2.84.

$$\frac{\$224,723}{\$79,056} = \$2.84$$

Source: Partners in Loyalty Marketing Inc, "Q1 2013 Program Evaluations Measuring ROI," July 26, 2013, p. 18.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Janssen's Speaker Program Results: Significant Impact on Sales

Revenue per Rx

Speaker Program	Thru Nov'11	Jan - Nov 2012	Q1 2013
Total NTS lift	\$ 7,709,853	\$ 4,346,270	\$ 224,723
Total TRx lift	11,174	6,299	299
Revenue per Rx	\$ 690	\$ 690	\$ 752

Screenshot from PILM Report:¹

► Speaker Programs are an effective way to make a lasting impact on prescribing behavior

Revenue per dollar spent

Speaker Program	Thru Nov'11	Jan - Nov 2012	Q1 2013
Total NTS lift	\$ 7,709,853	\$ 4,346,270	\$ 224,723
Investment	\$ 2,655,569	\$ 1,381,906	\$ 79,056
Bottom line ROI	\$ 2.90	\$ 3.15	\$ 2.84

In contrast to Janssen's Expert, PILM clearly concludes Speaker Programs have a lasting impact on prescribing behavior.

(1) Partners in Loyalty Marketing Inc, "2012 Program Evaluations Measuring ROI," January 22, 2013, p. 23.

PILM's Return-on-Investment Analysis of Janssen's Marketing

Sales Force Results: Significant Impact on Sales

Screenshot from PILM Report:

- ▶ **110 Sales Reps called on 4,925 targets in 2012**
 - ▶ **Each HCP generated 5.61 incremental TRx – topping all programs**
- ✓ This is the strongest Sales Force lift PILM has seen across evaluated pharma brands

Source: Partners in Loyalty Marketing Inc, "2012 Program Evaluations Measuring ROI," January 22, 2013, p. 29.

PILM's Return-on-Investment Analysis of Janssen's Marketing

PILM's Conclusion on Program's Impact on Both P&I

Screenshot from PILM Report:¹

► Interestingly, Intelence Speaker Programs also had impact on Prezista TRx lift
✓ 13.72 TRx per HCP

(1) Partners In Loyalty Marketing Inc., "2011 Program Evaluations Measuring ROI," April 20, 2012, p. 23.

Damages: Kickbacks and Off-Label Marketing

Damages Resulting From Kickbacks and Off-label Marketing

Kickbacks

Janssen providing
kickbacks to speakers



Effect: Speakers
prescribing P&I Rx

Off-label Marketing

Janssen marketing
off-label to physicians



Effect: Influenced
physicians initiating
off-label P&I Rx

Kickback Damages

Reimbursed by Government Payors: Medicare, Medicaid and ADAP

Kickback Damages Calculation

Once a speaker was paid by Janssen, all P&I Rx made by that speaker, and which were reimbursed by the government, are considered damages (from the first payment through 2014).

Kickback Claims:
435,042



**Kickback
Damages
\$ 327.2 million**

Note: Based on 321 speakers who had a known National Provider Identifier ("NPI") number (Medicare, Medicaid and ADAP).

Off-Label P&I Claims:

1) Prezista Lipids (2006-2014)

All Prezista Rx, written for patients who received any lipid regulating medication or a lipid-related diagnosis prior to the first time they were prescribed Prezista.

2) Prezista Treatment Naïve (2006-2008)

All Prezista Rx, written for patients who previously were not taking any ARV medication.

3) Intelence Treatment Naïve (2008-2014)

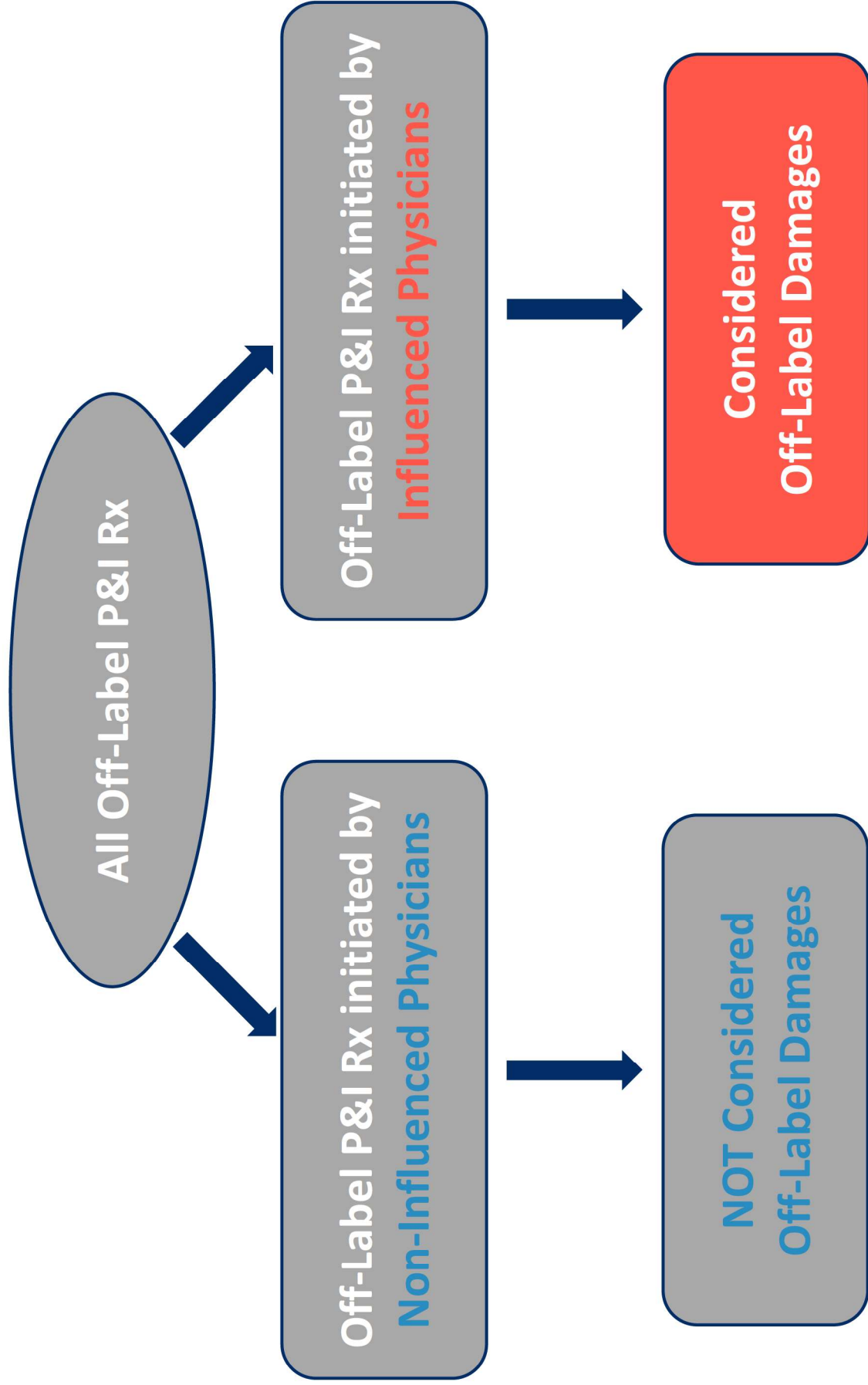
All Intelence Rx, written for patients who previously were not taking any ARV medication.

4) Intelence Once-Daily Dosing (2008-2014)

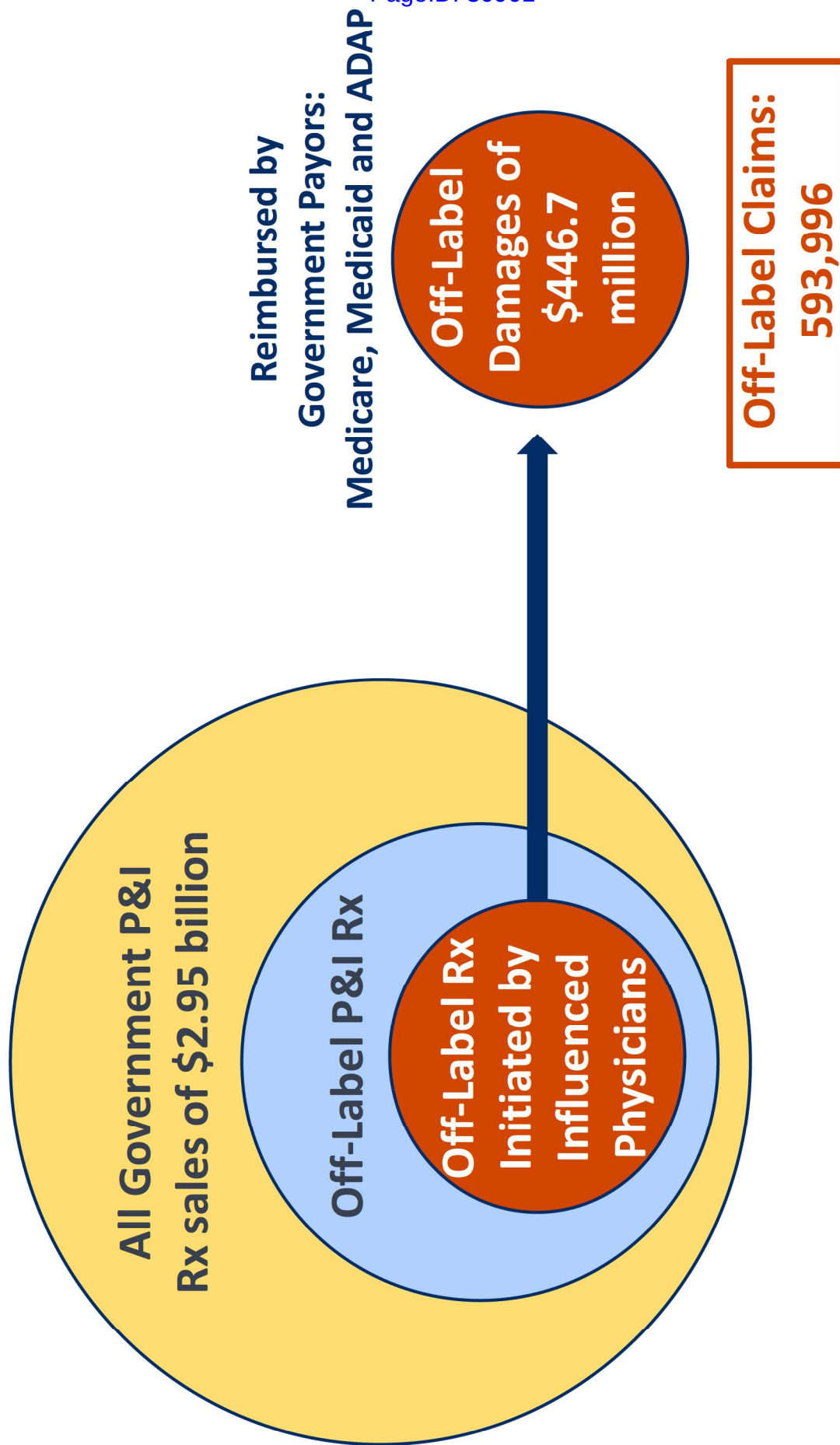
All Intelence Rx with dosing instructions providing once-daily usage.

Off-label P&I Damages

Reimbursed by Government Payors: Medicare, Medicaid and ADAP



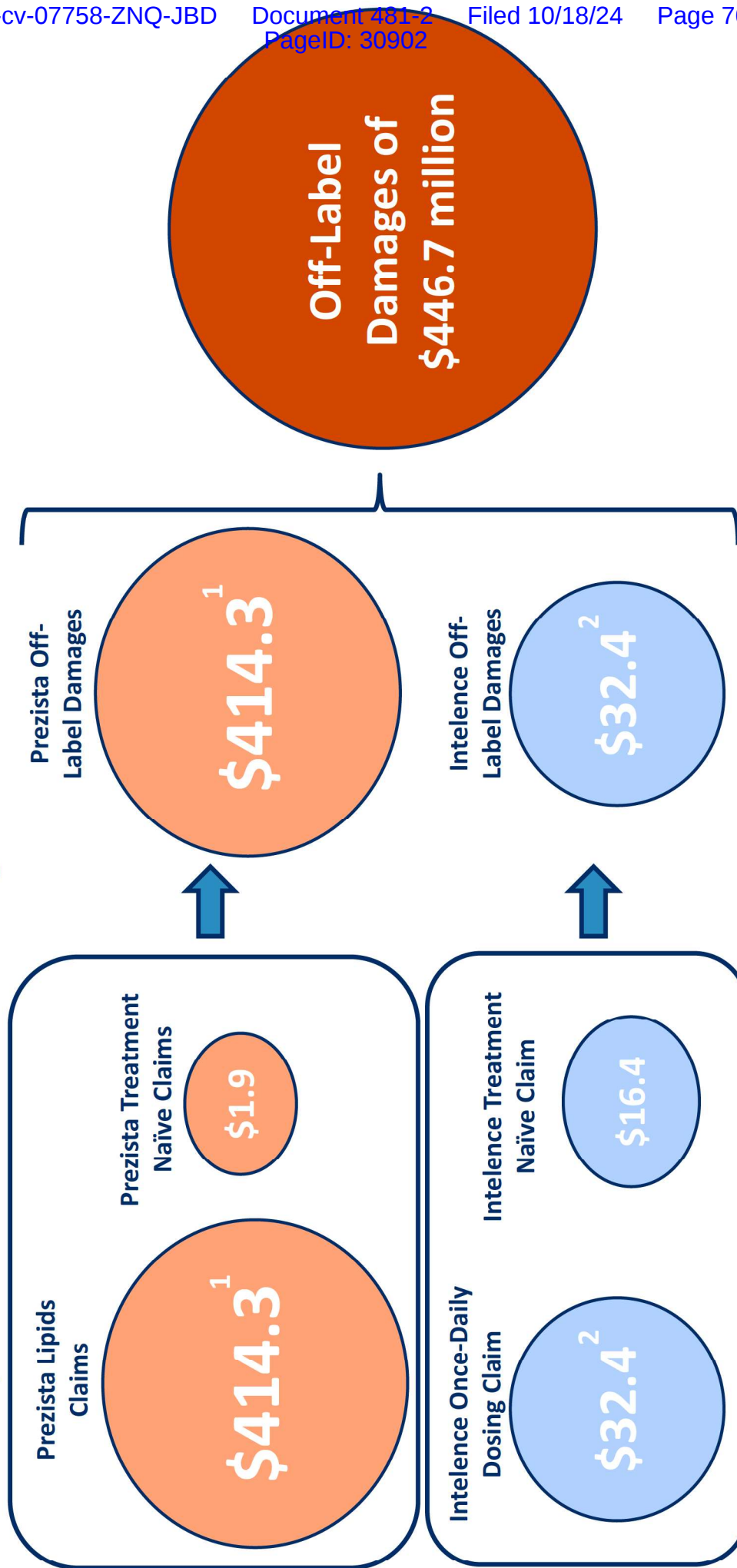
Off-label Damages (2006-2014)



Off-label Damages (\$ millions)

Reimbursed by Government Payors: Medicare, Medicaid and ADAP

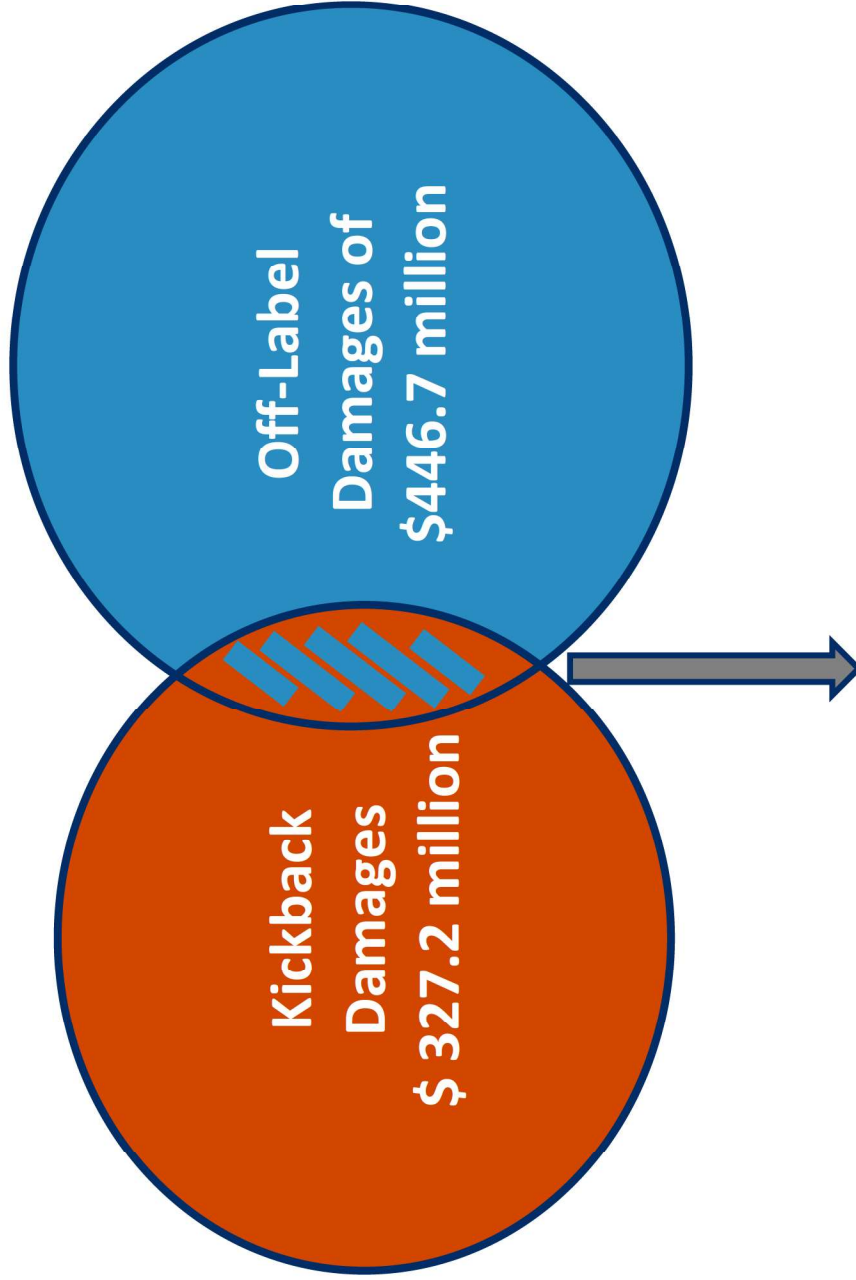
Conservatively Excluded Certain Off-Label Damages



(1) Hyperglycemia codes were eliminated from the analysis, which lowered Prezista lipids damages from \$430.4 million to \$414.3 million.

(2) Includes only Intelence Once-Daily Rx that were initiated by influenced physicians.

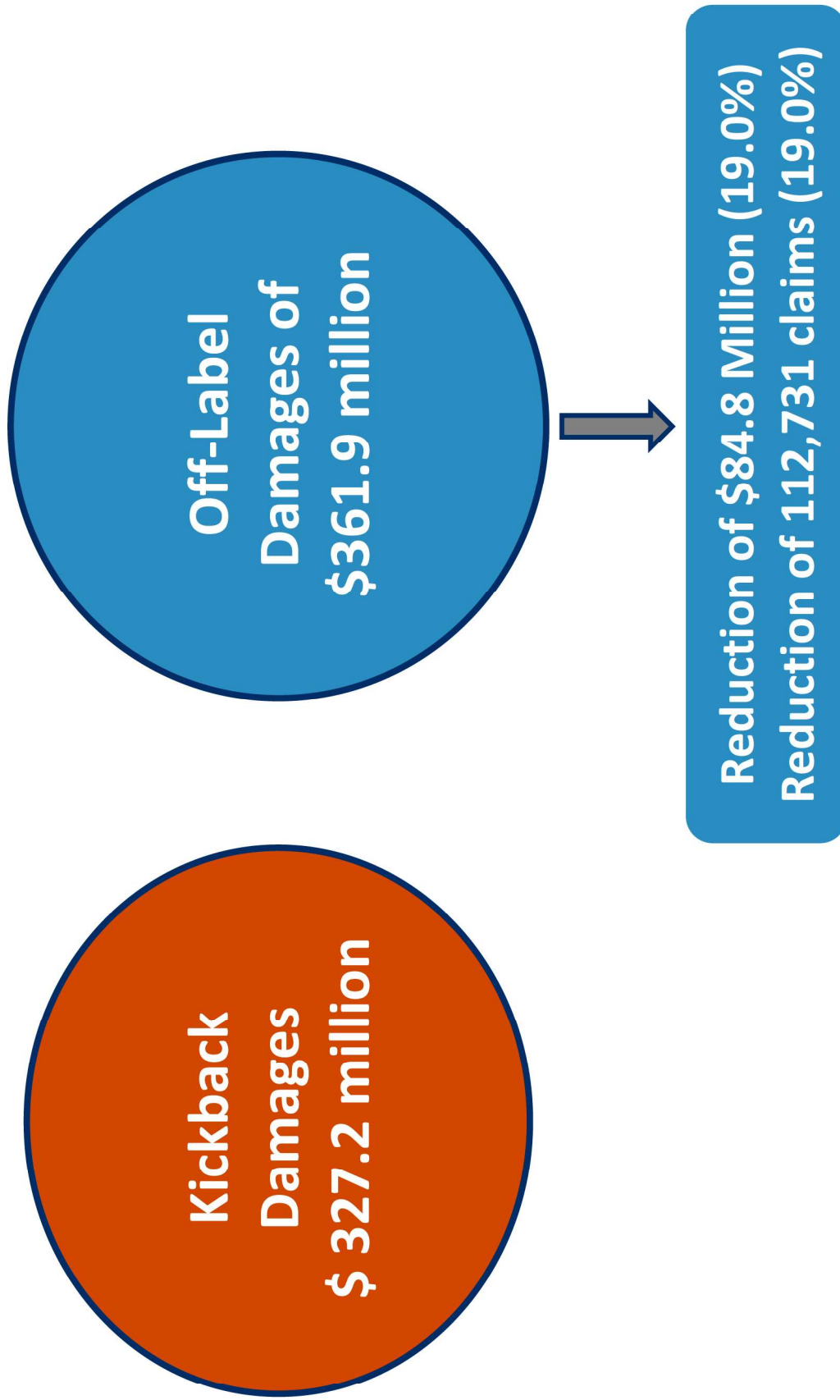
Deduplication of Off-Label and Kickback Damages



Excluded From Damages Calculation:

Overlap of \$84.8 million between kickback and off-label damages represents off-label claims initiated and written by speakers.

Deduplication of Off-Label and Kickback Damages



Deduplication of Off-Label and Kickback Damages

**Kickback Claims:
435,042**

**Reduced Off-
Label Claims:
481,265**

**Kickback
Damages
\$ 327.2 million**

**Reduced Off-Label
Damages of
\$361.9 million**